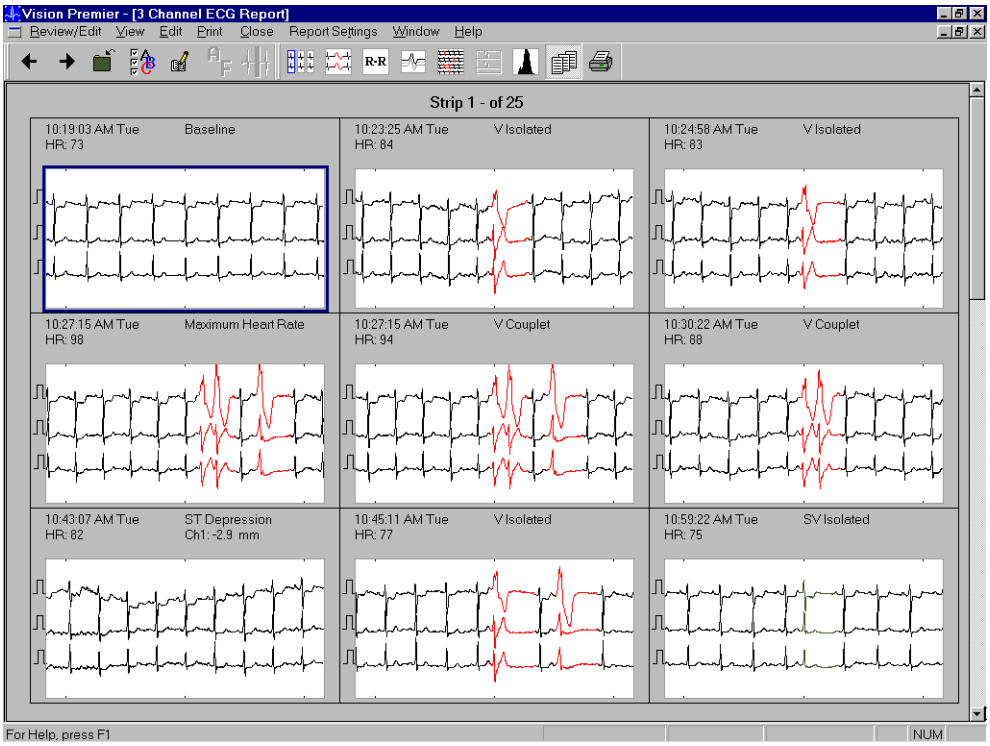
Operating Instructions



Vision Premier™
Holter Analysis System
Software Version 3.3

Operating Instructions Part No. 086558
Revision: 0103

DISCLAIMER

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Table of Contents

Intended Use

> **NOTICE:** This device is intended to be used as a Holter Monitor Analysis System for the purpose of screening for ECG rhythm disturbances. It should be used by or under the supervision of those knowledgeable in all aspects of ECG morphology, rhythm and arrhythmia.

This device is intended to be used under the supervision of a qualified physician. The Vision Premier™ Holter analysis system may be used in conjunction with standard 12-lead ECG analysis as an additional means for identifying heart disease. The extended recording period for Holter data provides a great deal more data than the standard 10-second ECG recording. A Holter recording captures abnormalities which may be infrequent or provoked by specific activities.

Suggested indications for conducting Holter analysis include:

- ✔ Arrhythmias
- ✔ Chest pain
- ✔ Unexplained syncope
- ✔ Shortness of breath
- ✔ Palpitations
- ✔ Evaluation of a pacemaker
- ✔ Regulation of antiarrhythmic drugs
- ✔ Evaluation of a patient after myocardial infarction
- ✔ Family history of heart disease

The Vision Premier™ system uses a sophisticated algorithm to detect, measure and classify QRS complexes. Each beat is classified and grouped into classifications called forms.

After the Vision Premier™ system has performed its analysis of the data, you may then review and change the system's classification.

When editing has been completed, the Vision Premier™ system automatically recompiles the report and incorporates your changes into the final results. All aspects of the report are affected; hourly totals and beat totals.

> **NOTICE:** Computer assisted analysis is a valuable tool when used properly. However, no automated analysis is completely reliable and the results should be reviewed by a qualified physician before treatment, or non-treatment, of any patient.

Software Version

This manual contains instructions for using Version 3.3 of the Vision Premier™ software. To check the version of the software you have installed on your system, perform the following steps:

1. From the Windows desktop, double-click the program icon. This will start the program.
2. Under Help on the menu bar, select About Vision Premier... The software version is indicated in the window that appears.

Electronic Manuals

Vision Premier™ software includes electronic manuals, if this optional feature has been installed. To access electronic manuals, including the Vision Series Setup Guide, Vision Premier Operating Instructions, and Holter recorder Operating Instructions, perform the following steps:

1. From the Windows desktop, double-click the program icon. This will start the program.
2. Under Help on the menu bar, select Setup Guide or one of the other manuals that are listed.

   NOTE: The Operating Instructions is listed as Main Manual.

Warnings, Cautions & Notices

Warnings

WARNING: Most waveform displays are not diagnostic quality. Due to monitor video resolution, waveforms displayed on the monitor are for viewing purposes only. To view data that is diagnostic quality, use the report strip view or print the record.

WARNING: Remove all Holter sensors from the patient before defibrillation. There is a risk of defibrillation failure, burns and equipment damage if defibrillator paddles contact sensors or cables. In the special case where the patient has a defibrillator at home, family members and in-home caregivers who could be responsible for attempting defibrillation must be advised of this hazard.

WARNING: Explosion hazard. Do NOT use in the presence of flammable anesthetics.

Cautions

CAUTION: Vision Series research mode is available for use with the 6632 and 92510 digital recorders only. Attempts to use any other Burdick recorders in research mode will result in erroneous data.

CAUTION: Edits made directly to Holter report e-mail attachments cannot be saved. To edit Holter reports received via e-mail, first save the attached report to a secure file location (requires an .rps file extension).

CAUTION: Do NOT use acetone, ether, freon, petroleum derivatives or other solvents to clean the recorder.

CAUTION: Holter data acquired on cassette tapes is directly affected by the condition of the cassette tape, the tape recorder and the tape playback unit. To ensure that a reliable analysis is made, regularly clean the recorder and playback unit and always use Burdick Holter cassette tapes. NEVER reuse cassette tapes.

CAUTION: Although Burdick, Inc. recorders are designed to meet IEC 601-1-2 EMC immunity requirements, the presence of strong EMI fields generated by electronic, surgical or diathermy instruments in close proximity to the unit may cause trace noise or input overload conditions.

CAUTION: To avoid operator injury refer to you PC owners manual for proper ergometric use.

Notices

NOTICE: U.S Federal law restricts this device to use by or on the order of a physician.

NOTICE: Computer assisted analysis is a valuable tool when used properly. However, no automated analysis is completely reliable and results should be reviewed by a qualified physician before treatment, or non-treatment, of any patient.

NOTICE: Because the Holter system offers different lead configurations, always ensure that the appropriate sensor placement is employed for the lead configuration selected.

NOTICE: This device is intended to be used as a Holter Monitor Analysis System for the purpose of screening for ECG rhythm disturbances. It should be used by or under the supervision of those knowledgeable in all aspects of ECG morphology, rhythm and arrhythmia.

Chapter 1 *Introduction to Vision Premier™*

Inspection Upon Delivery

Your new Vision Premier™ Holter Analysis system was carefully inspected before shipment. Please inspect all components upon delivery for any damage which may have occurred in transit. If you notice any damage, please contact your shipping agent. If items are missing, contact your local representative or call Burdick Customer Service at (800) 284-4362 or (608) 764-2396.

> **NOTE:** Your Vision Premier™ system is intended for use with approved supplies; its reliability and performance are directly affected by the supplies you use.

All functions of the Vision Premier™ system are designed to be user-friendly and easy to understand. If questions arise or you would like additional information, contact your local representative or Burdick Technical Support Department at (800) 333-7770 or (608)764-1919.

CE 0123 Meets or exceeds Council Directive 93/42/EEC, MDD, Class IIa.

Complies with the EMC/Radiocommunications requirements set out by the Australian Communication Authority under Radiocommunications Act, 1992.

System Requirements

In order to run the Vision Premier™ program your computer system will need to meet minimum requirements. For more information, refer to Chapter 1 of the Vision Series Setup Guide.

Starting the Program

NOTE: Reference your PC/ peripheral manual for hardware installation.

Starting from the Icon on the Desktop

1. Turn on your computer.
2. Double click on the Spacelabs Holter System icon to start the program.

3. The Vision Premier™ program is started and the ***Report Manager*** window is displayed.

Exiting the Program

To exit, click on Procedure then select Exit in the Vision Premier™ ***Report Manager*** window. The Windows® desktop is displayed.

Removing the PC Card

If you are using an internal PC Card to acquire patient records, you must deactivate the PC Card drive before removing the PC Card from the computer.

NOTE: The following procedure applies for internal PC Card drives only. Disregard the following if you are using an external PC Card drive.

1. To deactivate the PC Card drive, click on the PC Card symbol in the lower right corner of the desktop.
2. Click on the [Stop PCMCIA Card] option.
3. When the PC Card is deactivated, Windows® will display a confirmation message. Click [OK] and remove the PC Card from the computer.

Search by Time

You can search for specific times in the Holter report using the graphic summary view. Time is indicated near the bottom of the window. Locate the desired time and double click to view the beats. For additional information, see “Graphic Summary” on pg. 5-8 and “Displaying the Full Disclosure” on pg. 8-1.

Running Vision Premier Remotely

Vision Series software supports the use of remote Windows operation using third party software, such as Symantec pcAnywhere™. For information on installing and configuring pcAnywhere, refer to the Vision Series Setup Guide.

Using the Mouse

Although many operations on the Vision Premier™ system may be carried out using the keyboard, the mouse is usually more convenient. Before using Vision Premier™ you may want to familiarize yourself with how the mouse works.

Moving

When moving the mouse, you might simply think of it as a holder for the small ball which can be seen on the underside of the mouse. The best arrangement for the mouse is ball side down on a flat mouse pad with the cord pointing away from you. In this position, the ball rolls along the pad whenever you move the mouse.

When Vision Premier™ is on, the screen always displays a pointer which moves as the mouse ball rolls. If you move the mouse off the mouse pad, simply pick up the mouse and place it back on the pad. Lifting the mouse stops the ball from rolling and keeps it from moving the pointer.

This pointer is usually a small arrowhead () which is positioned over objects when selecting them. Sometimes it is an I-beam () which is used to position the cursor for typing in edit fields.

Clicking

Locate the mouse under the palm of your hand with the cord pointing away from you.

The Left and Right Mouse Buttons

Notice that the mouse has either two or three buttons. When the mouse is positioned with the cord pointing away from you, the button to the left is the most commonly used button. We will refer to this button as the left mouse button and the one to the right as the right mouse button. If your mouse has three buttons, the center one is not used by the Vision Premier™ system.

Click

To "click," press and release the left mouse button. You should feel and hear the button click.

Right Click

Most operations require the left mouse button but some special operations can be done with the right mouse button (see "Context Menus" on pg. 1-7).

In this manual, using the right mouse button will be referred to as "right clicking." To "right click," press and release the right mouse button. You should feel and hear the button click.

Double Click

To "double click," press and release the left button twice without pausing. Do this quickly. Double clicking takes less than one second.

Getting Around

The Vision Premier™ system follows Microsoft Windows conventions for manipulating files and issuing commands. When you start the program, two windows are displayed, one for the application and one for the report manager. The application window includes the title and menu bars, toolbar, control-menu box, minimize and maximize/restore buttons and, when necessary, vertical and horizontal scroll bars. The ***Report Manager*** window has only its own title bar and window controls.

You can move around within each window by dragging or clicking the scroll bars, and can resize each window by clicking and dragging the borders and corners. Click and drag the title bar to move the window itself about. To reduce the active window to an icon, select Minimize from the control-menu box or the Minimize button. To have the window fill the screen, click on the Maximize button. (***Report*** windows are always maximized when they are first opened.)

The program will display multiple, independent windows, so you can have several different reports open at once. Each report will have its own window and can be separately moved, resized, opened and closed, and printed. To make a window active, just click on it, or press CTRL-TAB to cycle through the open windows.

Objects are special items displayed on the screen. You can use these items to interact with the system:

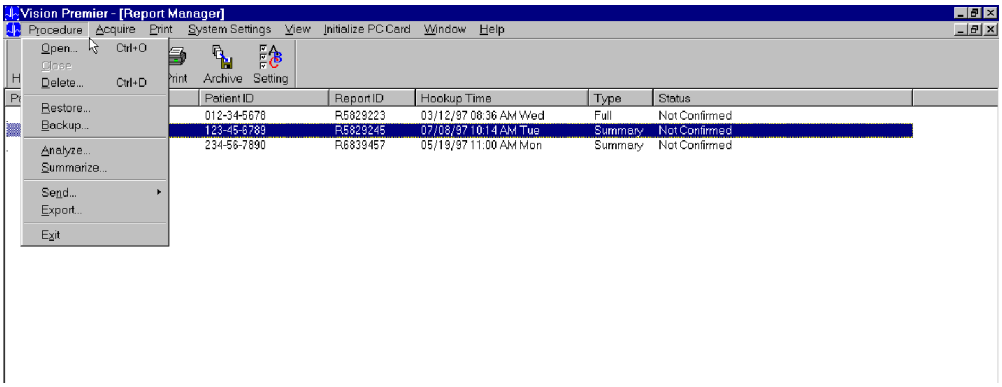
- Menu Bars
- Toolbars
- Context Menus
- Dialog Boxes
- Confirmation Boxes

> **NOTE:** When an object appears lighter than the rest, or grayed-out, this means that the object is not available. An object may be unavailable if:
>
> ✔ Vision Premier™ is not in the appropriate mode to utilize that object.
>
> ✔ Your version of Vision Premier™ does not support the object's function.

Menu Bars

Menu bars may be used to select an item such as a new window or to select a function such as acquiring a new record from the Holter recorder.

Figure 1-1
Menu Bar



Menu bars contain two basic types of commands. “Executing” commands carry out tasks immediately when selected and “Dialog box” commands, followed by an ellipsis (…), bring up dialog boxes.

You can use either the mouse or the keyboard to activate and use menu commands.

Using the Mouse

1. Position the pointer over the menu bar item and click. More choices become available.
2. Click on one of these items to select it or click anywhere outside the menu bar to cancel.

Using the Keyboard

1. To activate a menu bar item, hold down the ALT key and press the appropriate “hot key.”

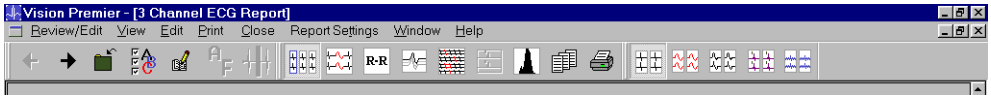
   A hot key is a key on the keyboard which is temporarily specialized to perform a function. To indicate which key will perform this function, a letter is underlined. For example, R is the hot key which activates the Procedure menu bar item.
2. To select an item from the pull down menu that appears, press the appropriate hot key. (ALT is not needed once the pull down menu is activated.)

   Instead of hot keys, you may use the ↑ and ↓ keys on the right side of the keyboard. With these keys, highlight the desired item and press ENTER to select it.
3. You may deactivate pull down menus by pressing ALT or moving to other menus with the ← or → key on the right side of the keyboard.

Toolbars

Toolbars are a row (or rows) of icons located just below the menu bar. Toolbar icons are provided to allow you to initiate a function or to advance to another window with just a single click of the mouse. All of the icons have a corresponding menu bar and/or drop down menu which will perform the same function.

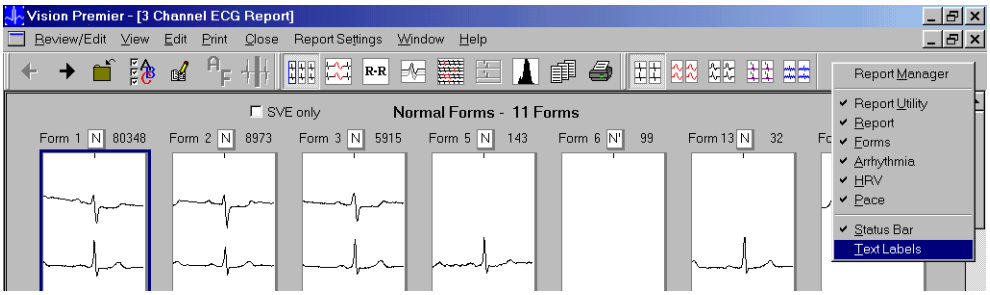
Figure 1-2
Toolbar



The icons presented in the Vision Premier™ system toolbar change according to what is shown in the active window. For example, if you are currently reviewing forms, you are presented with additional icons to enable you to quickly switch to another type of form.

You have the option of choosing which toolbars are displayed and whether or not the text labels are on or off. To change these options, point the mouse anywhere in the toolbar area and right click. A context menu will appear. Options are active when they have a check mark next to the name. If you make any changes to these options, your selections will become active after the program has been restarted.

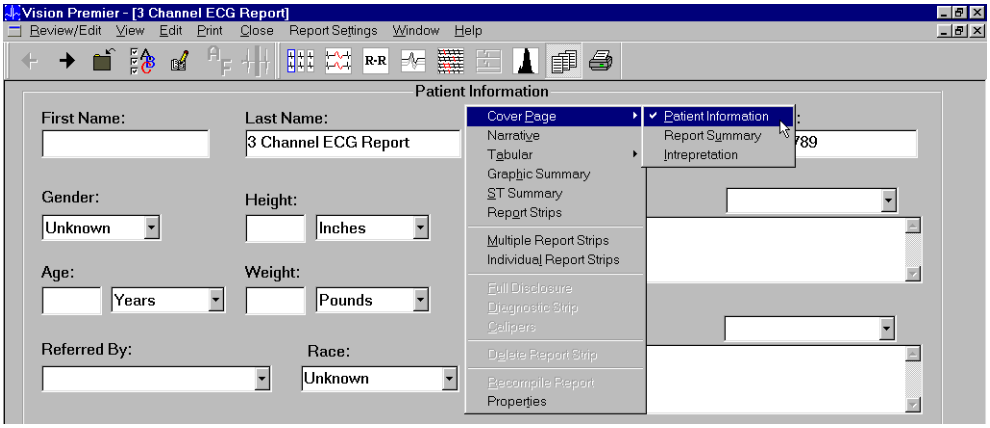
Figure 1-3
Toolbar Options



Context Menus

A context menu is a list of functions available to you in context to whatever you are pointing the mouse at when you activate the menu. You can activate a context menu by right clicking within a window. Not all windows have context menus.

Figure 1-4
Context Menu



Dialog Boxes

Dialog boxes are used to enter information by typing in edit fields, picking from pull-down menus, or selecting check boxes or radio buttons. Dialog boxes also include buttons for indicating you are finished and want the program to accept the new settings or to escape without making any changes.

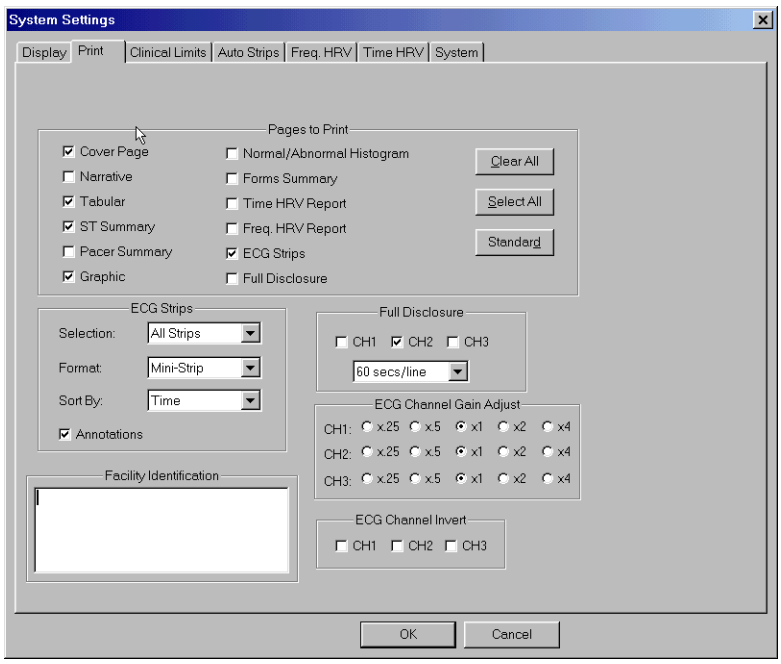
Dialog boxes may include any or all of the following objects:

- Edit Fields
- List Boxes
- Check Boxes
- Radio Buttons
- Tabs

Edit Fields

An edit field is a box where you can enter text from the keyboard. To view a window with edit fields, click on the System Settings icon in the toolbar of the ***Report Manager*** window.

Figure 1-5
Edit Field



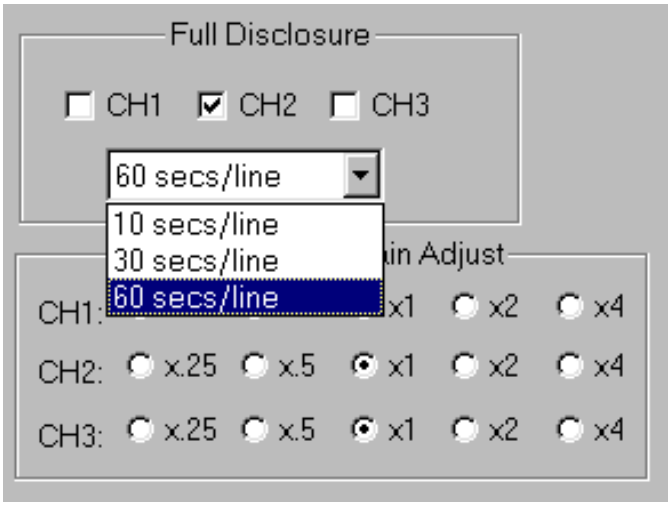
The Facility Identification field is an Edit field. Move the mouse pointer into this field and click to activate the field. Notice that the pointer turns into an I-beam ( ) in these fields. Edit fields accept text from the keyboard when they are active. This is indicated by a blinking cursor at the insertion point. Start typing and the characters you type are placed into the box.

Space in edit fields is limited. Each edit field accepts a specific type of information. For example, some accept only numbers within a preset range. If you type invalid information, a dialog box will inform you of the problem.

List Boxes

A list box is a box with a list of available choices. An example of a list box is shown for the Full Disclosure option in the Print tab of the ***System Settings*** window.

Figure 1-6
List Box



List boxes are not fully displayed until activated by clicking the expand button ( ). To select an item from a list, position the pointer over the item and click. Click outside the list to deactivate it.

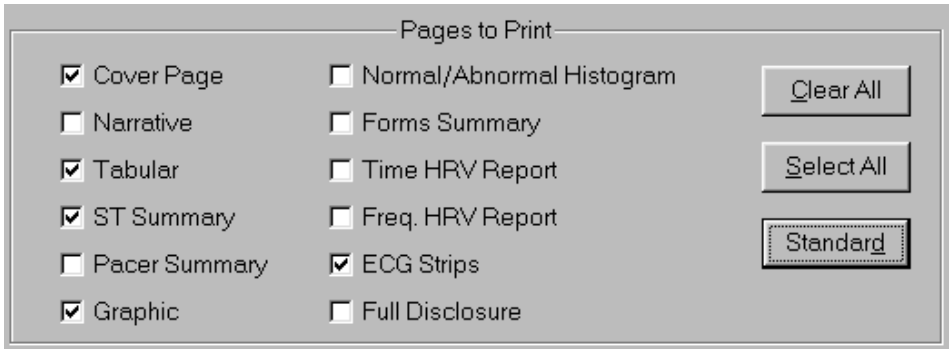
You can create or add to some of the lists that are available on the Vision Premier™ system. Most of these user-editable lists are found in the ***Patient Demographic Information*** and the ***Miscellaneous Data*** windows. These lists are identified by a special expand button ( ). Click this button to access the window where the list can be edited.

Check Boxes

A check box is a small square object.

Check boxes are either selected or unselected. A selected check box is indicated by a check mark. Click in the check box to select or deselect that item. Any number of check boxes may be selected.

Figure 1-7
Check Boxes

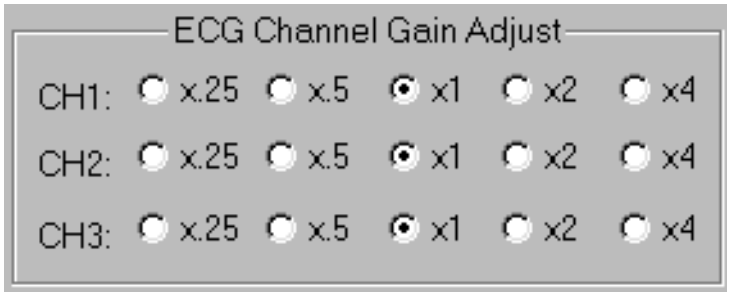


Radio Buttons

A radio button is a small round object that is always displayed in a group of two or more, mutually exclusive buttons.

Like check boxes, radio buttons are either selected or unselected. A selected radio button is indicated by a filled-in dot. Unlike check boxes, selecting one radio button in a group causes any other radio button in that group to become unselected. Click on the radio button to select the desired item.

Figure 1-8
Radio Buttons

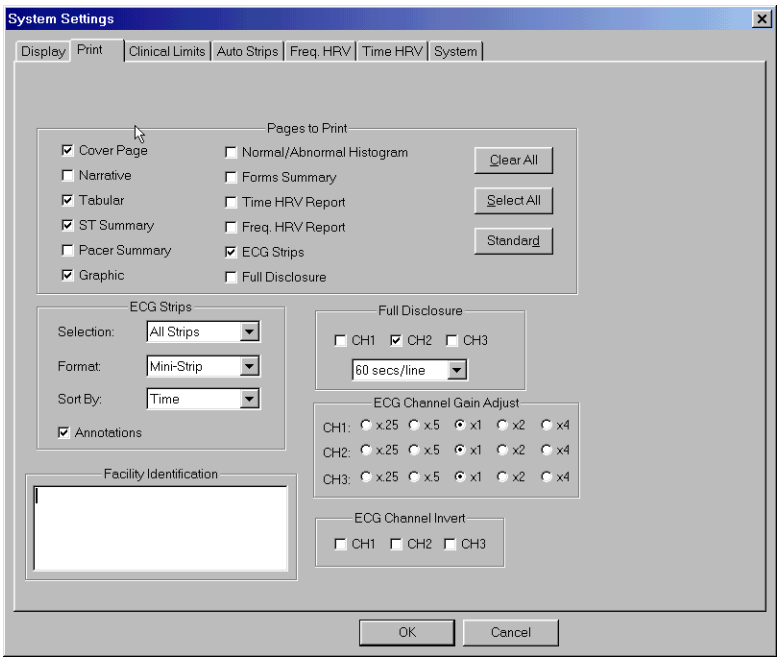


Tabs

Some windows have more information in them than can be displayed at one time. The problem of displaying all the information is handled by using tabs.

Windows with tabs have multiple "pages" that are overlapping. A tab from each page is visible at all times. You can click on the tab to display the corresponding page.

Figure 1-9
Tabs

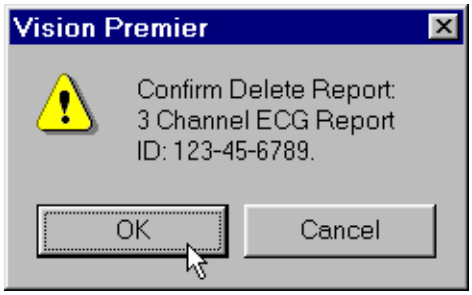


Confirmation Boxes

A confirmation box is a small window with just one or two buttons, usually [OK] alone or both [OK] and [Cancel] together. These boxes provide you with information or ask you to verify an action. They disappear after you select a button.

An example of a confirmation box is displayed if you try to delete a record in the ***Report Manager*** window.

Figure 1-10
Dialog Box



You must respond to a confirmation box in order to continue working. In the above example you must click [OK] or [Cancel] to acknowledge the message.

Chapter 2 *PC Card Recording Preparation*

To prepare for a patient recording, you must prepare the recorder and connect the recorder to the patient. Please refer to the Operating Instructions that came with your recorder for further information. If you are using a PC Card recorder, the PC Card must be initialized prior to being inserted into the recorder.

The Vision Premier™ system provides two methods for initializing the PC Card. If you are experienced with patient hookup and PC Card initialization, follow the instructions given in ""Initializing the PC Card"" below. The Vision Premier™ system also offers a "Hookup Wizard" to guide you through all of the steps necessary to ensure accurate recording results. (For more information, see "Hookup Wizard - Digital Recorder" on pg. 2-5 or "Hookup Wizard - Tape Recorder" on pg. 2-10.)

Initializing the PC Card

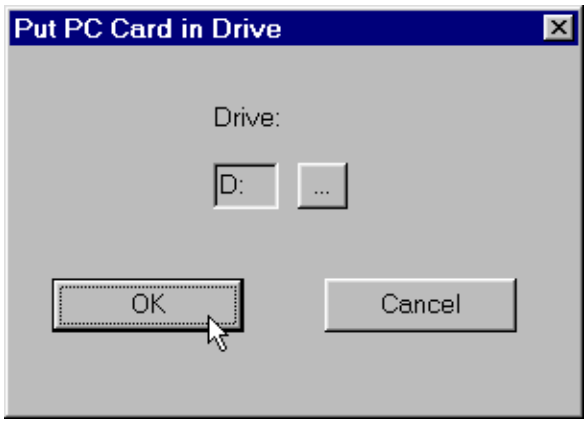
To record data from a patient you must first prepare the PC Card. This process is called Initialization.

NOTE: If, at any time, you are unable to proceed to the next step refer to "Maintenance & Troubleshooting" on pg. 14-1.

1. Remove the PC Card from the recorder and place it in the PC Card slot in your computer.
2. Start the Vision Premier™ program. The ***Report Manager*** window is displayed.
3. Select Initialize PC Card from the Menu bar.

NOTE: If a PC Card is not inserted into PC Card drive, a dialog will appear requesting you to insert a PC Card. This dialog will also allow you to browse for the PC Card in case it is located in a different drive.

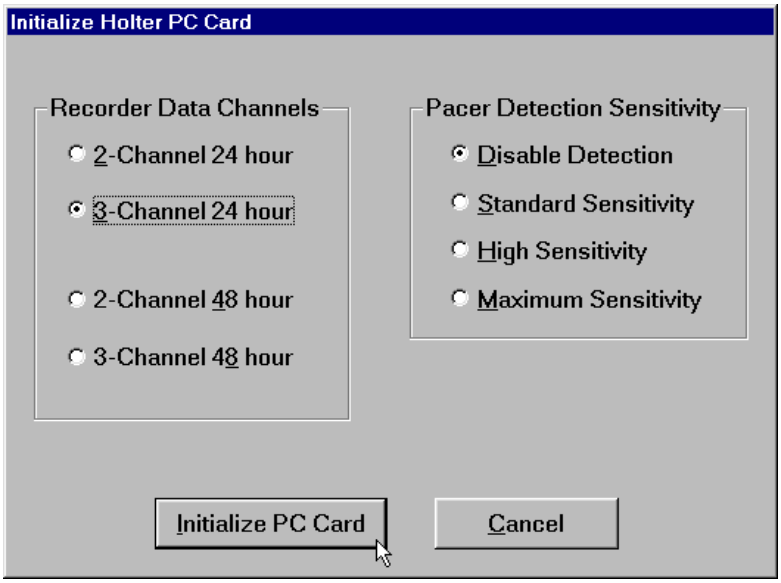
Figure 2-1
Insert PC Card Dialog Box



The ***Initialize Holter PC Card*** window is displayed.

NOTE: If the research license is installed, then the ***Select PC Card Acquisition Parameters*** window is displayed. For more information, refer to "Research Mode" on pg. 2-4.

Figure 2-2
PC Card Initialization Options



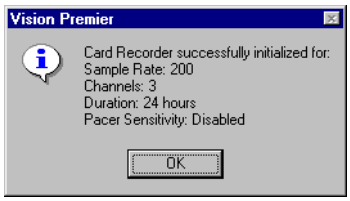
NOTE: Your Vision Premier™ system automatically recognizes the size of the PC Card being initialized and will grey out options not available to that specific card.

4. Select the appropriate number of recorder data channels and time duration to record by clicking the corresponding radio button.
5. If you have the optional Pacer software installed on your system, select the appropriate detection sensitivity. Refer to the Pacer Operating Instructions for more information.
6. Click [Initialize PC Card] to begin initialization. The ***Enter Patient Information*** window is presented.

   NOTE: The ***Enter Patient Information*** window will not appear if this feature has been disabled. If the window does not appear, proceed directly to step 7.

   Enter the patient's information into the window. When you are finished, click [OK]. For more information, see "The Enter Patient Information Window" on pg. 2-3.
7. When initialization is complete, a confirmation dialog box is displayed.

Figure 2-3
PC Card Initialization Confirmation

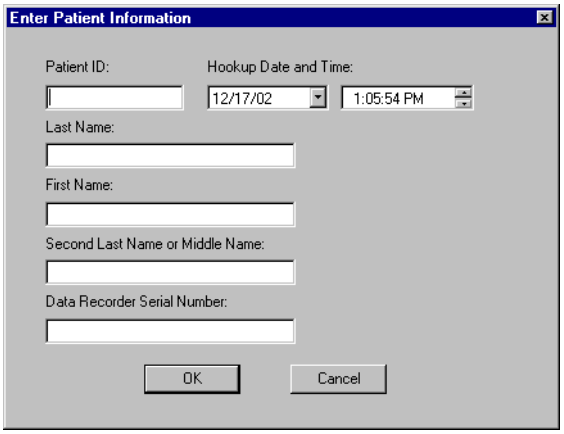


8. Click [OK].

   NOTE: If you are using an internal PC Card to acquire patient records, you must deactivate the PC Card drive before removing the PC Card from the computer. See "Removing the PC Card" on pg. 1-2 for more information.

The Enter Patient Information Window

Figure 2-4
Enter Patient Information



NOTE: Patient information entry is optional during initialization. You will also have the opportunity to enter patient information during record acquisition. If you prefer to enter patient information at a later time, click [Cancel].

Use the keyboard to enter information.

1. Enter the Patient ID (identification number).

   NOTE: If you do not enter a patient ID, Vision Premier™ automatically generates a patient ID that begins with **STAT#**. Patient ID, as well as other patient information fields, can also be edited when acquiring the patient record from the PC Card.

2. Click in the Last Name field and enter the patient's Last Name.
3. Click in the First Name field and enter the patient's First Name.
4. Click in the Second Last name or Middle Name field and enter the patient's second last name or middle name.
5. Click in the Data Recorder Serial Number field and enter the recorder serial number (this is located on the back or inside of the recorder).
6. The Hookup Date and Hookup Time are automatically filled in with the current date and time. Change this information if necessary.

7. When you are finished entering information, click [OK].

Research Mode

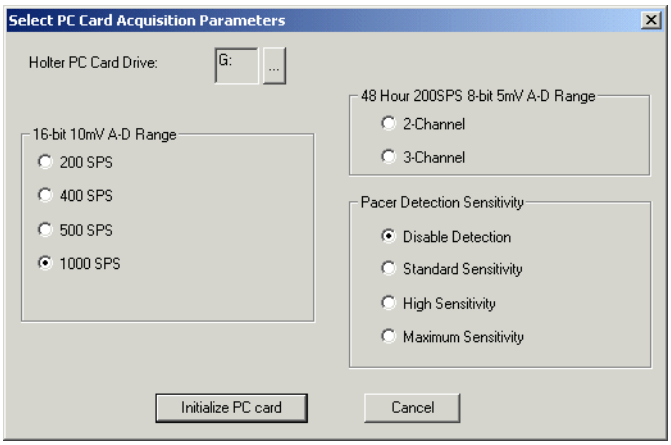
CAUTION: Vision Series research mode is available for use with the 6632 and 92510 digital recorders only. Attempts to use any other Burdick recorders in research mode will result in erroneous data.

NOTE: Research mode requires 256 MB or 512 MB PC Card.

NOTE: You always must select Initialize PC Card from the menu bar in order to utilize research mode features. If you use the Hookup Wizard, select Initialize PC Card after the Hookup Wizard window closes.

Research mode on Vision Premier™ allows you to initialize the digital recorder at a higher sample rate than is regularly used. During initialization, the ***Select PC Card Acquisition Parameters*** window appears instead of the ***Initialize Holter PC Card*** window.

Figure 2-5
Select PC Card Acquisition Parameters



1. Select sample rate acquisition parameters:

   ✔ Select a sample rate from the left side of the window

   or

   ✔ Select the appropriate number of channels (at 200SPS, etc.) from the top, right side of the window

2. If you have the optional Pacer software installed on your system, select the appropriate detection sensitivity. Refer to the Pacer Operating Instructions for more information.

Continue with step 6 on page 2-2.

Hookup Wizard - Digital Recorder

The Hookup Wizard includes three tiers of information:

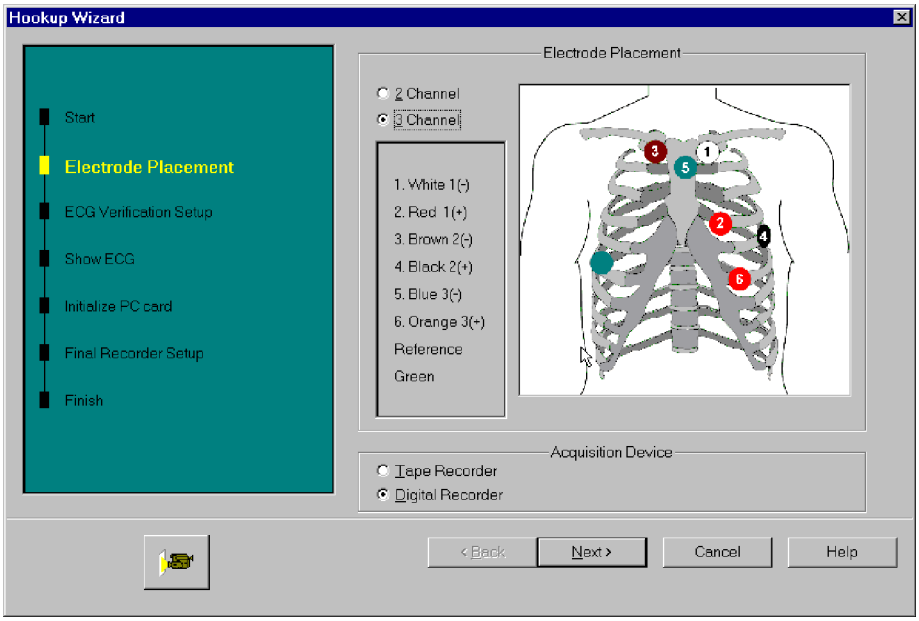
- ✔ an outline of all the necessary steps
- ✔ detailed instructions in for each step (text and/or graphics)
- ✔ on demand movies containing detailed instructions for each step

The Hookup Wizard guides you through all of the steps necessary to ensure accurate recording results. The wizard also initializes the PC Card for you. As the wizard guides you through the appropriate steps, you may press [Back] at anytime to review the previous steps and any choices you have made.

If you have installed the optional media player and video files, each screen will contain a Show Me icon ( ). Click on this icon anytime to view a short movie containing detailed instructions for performing the current step.

1. Start the Vision Premier™ program. The ***Report Manager*** window is displayed.
2. Insert a PC Card into the PC Card slot in the computer.
3. Click on the Hookup Wizard icon ( )in the toolbar. The ***Hookup Wizard*** is presented.

Figure 2-6
Hookup Wizard – Electrode Placement

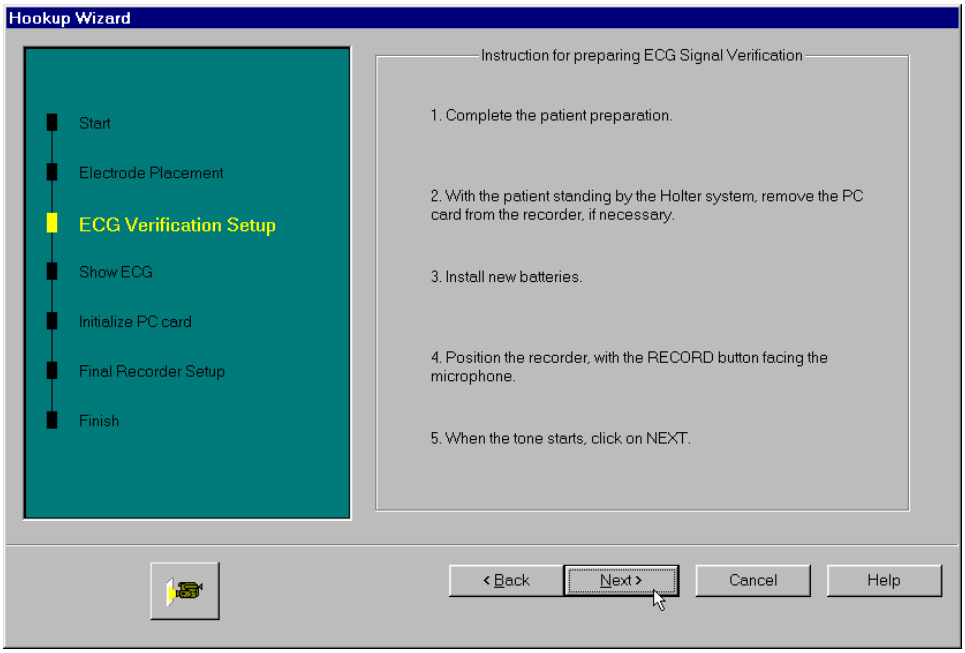


4. If you have a Tape Reader installed in your system, you are given the option of selecting Tape Recorder or Digital Recorder. Ensure Digital Recorder is selected.
5. Click on the appropriate radio button for either a 2-channel or a 3-channel hookup.
6. Attach the electrodes on the patient as indicated on the screen.

NOTE: Welch cups may be used at this point to eliminate waste of sensors during signal verification. The Welch cup will leave a red mark on the chest to aid in final placement of the sensor.

7. When you are satisfied that the electrodes are properly placed on the patient, click [Next]. The ***ECG Verification Setup*** screen is presented.

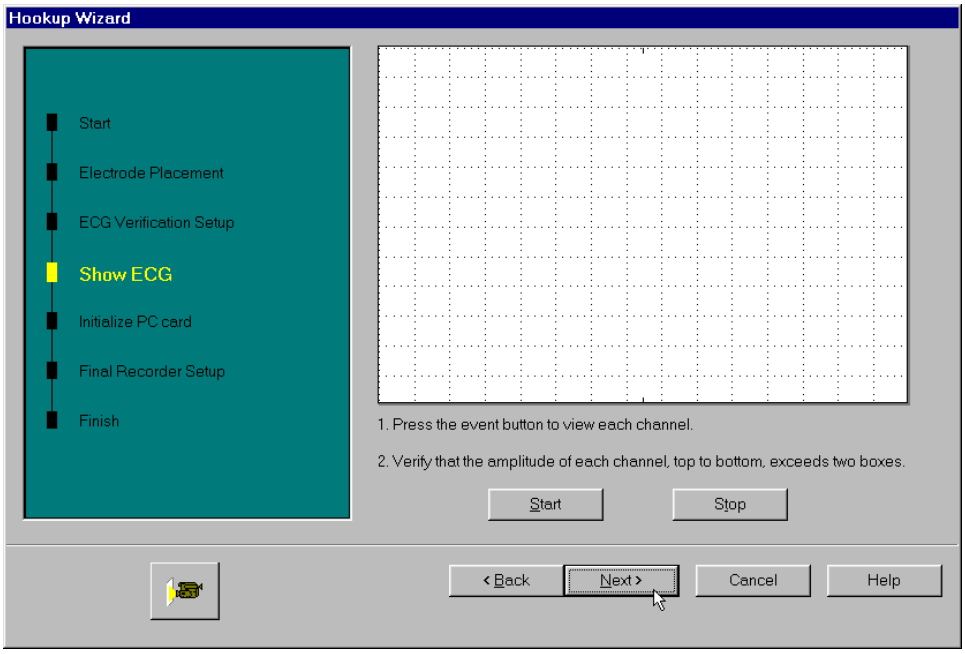
Figure 2-7
Hookup Wizard –
ECG Verification Setup



NOTE: Audio ECG Verification is only available for the Burdick 6722, 6732, 92512 and 92513 model recorders. If you are using any other recorder you should evaluate the signal quality using the procedures presented in the operating instructions for that recorder. Click [Next] as necessary to skip the ECG Signal Verification section of the wizard.

8. Follow the on-screen instructions for preparing the system for audio signal verification. Click [Next] when you are ready to verify the ECG signal. The Show ECG screen is presented.

Figure 2-8
Hookup Wizard – Show ECG



NOTE: The ***Show ECG*** screen is **not** a calibrated display. It is intended as a basic representation of the ECG signal to aid in the placement of the electrodes.

9. Turn on the power to the microphone.

10. Click [Start]. Press the Event button on the recorder to advance to the next channel.

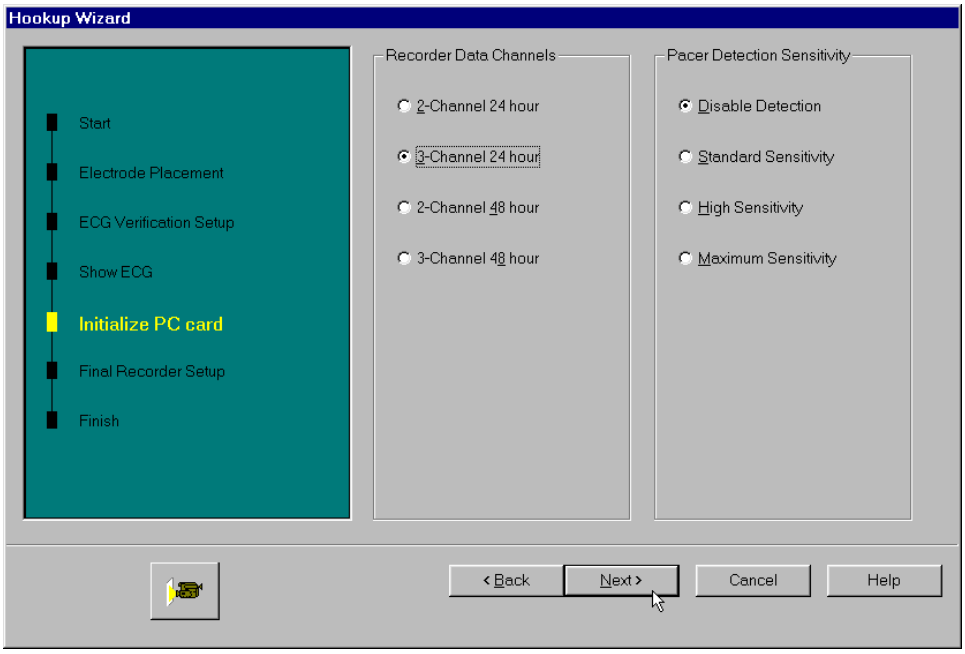
The recorder will beep to indicate the ECG channel that is about to be frequency modulated through the speaker (Channel 1 = 1 beep, Channel 2 = 2 beeps, Channel 3 = 3 beeps).

Verify that the amplitude of the signal for each channel is optimal. The best recordings are produced if the amplitude of the ECG signal is a minimum of two boxes and a maximum of four boxes on this display.

- ✔ To increase the amplitude in Holter channel 1, move the red sensor down and left of the sternum.
- ✔ To increase the amplitude in Holter channel 2, move the black sensor right (toward the sternum).
- ✔ To increase the amplitude in Holter channel 3, move the orange sensor right (toward the sternum).

11. When you are satisfied with the ECG signal quality, click [Stop], then click [Next]. The ***Initialize PC Card*** screen is presented.

Figure 2-9
Hookup Wizard – Initialize PC Card



NOTE: Your Vision Premier™ system automatically recognizes the size of the PC Card being initialized and will grey out options not available to that specific card.

12. Select the appropriate number of recorder data channels and time duration to record by clicking the corresponding radio button.
13. If you have the optional Pacer software installed on your system, select the appropriate detection sensitivity.
14. Click [Next]. The ***Enter Patient Information*** window is presented.

    NOTE: The ***Enter Patient Information*** window will not appear if this feature has been disabled. If the window does not appear, proceed directly to step 15.

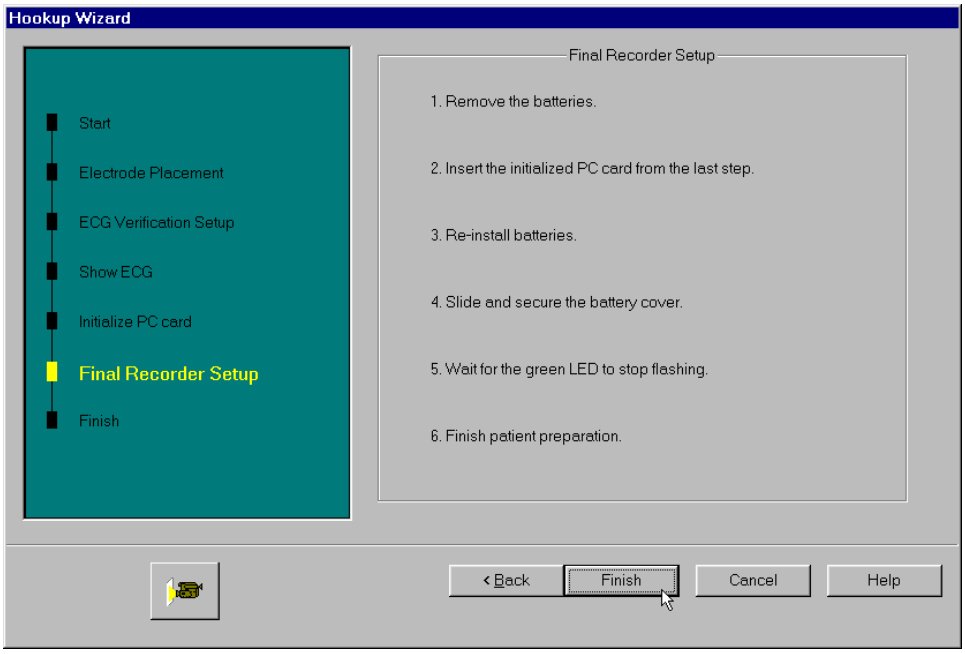
    Enter the patient's information into the window. When you are finished, click [OK]. For more information, see "The Enter Patient Information Window" on pg. 2-3.
15. When initialization is complete, a confirmation dialog box is displayed.

Figure 2-10
PC Card Initialization Confirmation

NOTE: If you are using an internal PC Card to acquire patient records, you must deactivate the PC Card drive before removing the PC Card from the computer. See "Removing the PC Card" on pg. 1-2 for more information.

16. Remove the PC Card and click [OK] to continue. The ***Final Recorder Setup*** screen is displayed.

Figure 2-11
Hookup Wizard – Final Recorder Setup



17. Follow the on-screen instructions for final recorder setup and click [Finish].

NOTE: The recorder is not ready until the green LED is steady on (i.e., on but not flashing).

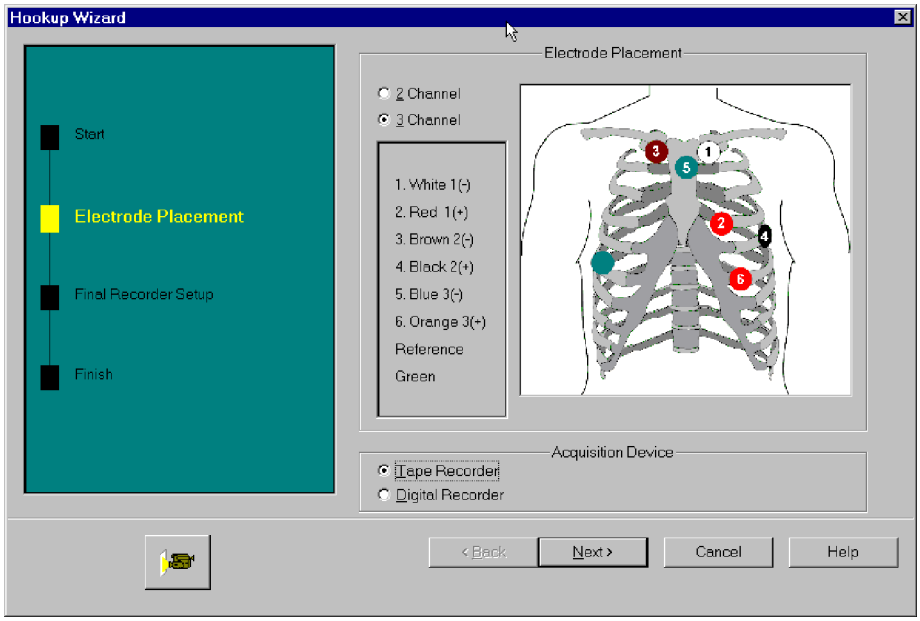
Hookup Wizard - Tape Recorder

The Hookup Wizard guides you through all of the steps necessary to ensure accurate recording results. As the wizard guides you through the appropriate steps, you may press [Back] at anytime to review the previous steps and any choices you have made.

If you have installed the optional media player and video files, each screen will contain a Show Me icon ( ). Click on this icon anytime to view a short movie containing detailed instructions for performing the current step.

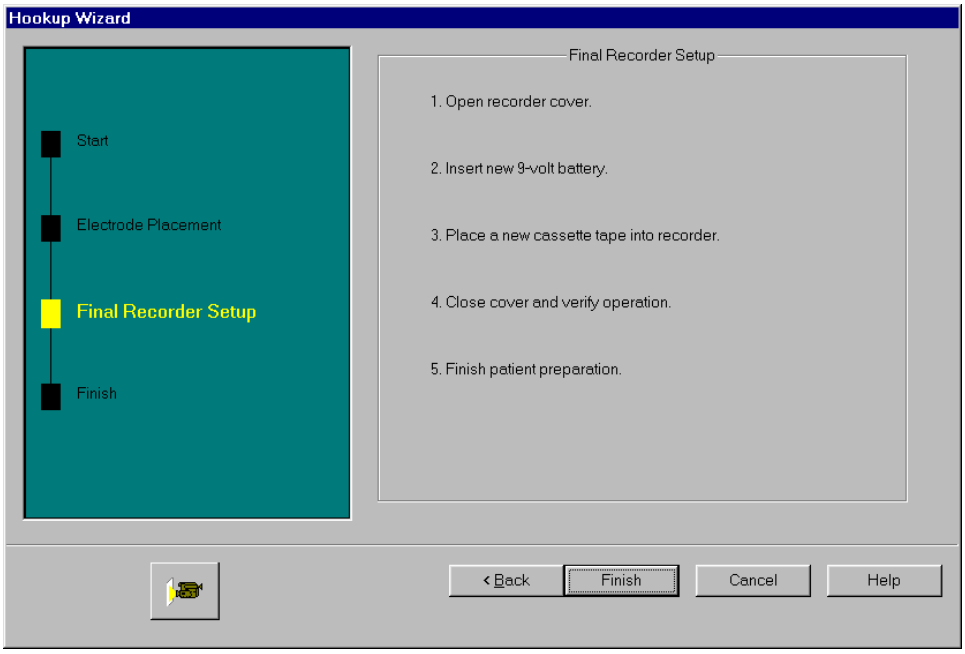
1. Start the Vision Premier™ program. The ***Report Manager*** window is displayed.
2. Insert a new Holter Cassette Tape into the Tape Reader in the computer.
3. Click on the Hookup Wizard icon ( )in the toolbar. The ***Hookup Wizard*** is presented.

Figure 2-12
Hookup Wizard – Electrode Placement



4. Ensure Tape Recorder is selected.
5. Click on the appropriate radio button for either a 2-channel or a 3-channel hookup.
6. Attach the electrodes on the patient as indicated on the screen.
7. When you are satisfied that the electrodes are properly placed on the patient, click [Next]. The ***Final Recorder Setup*** screen is presented.

Figure 2-13
Hookup Wizard –
Final Recorder Setup



8. Follow the on-screen instructions for final recorder setup and click [Finish].

Chapter 3 *Acquiring & Analyzing Patient Data*

After you have recorded data from a patient, you must copy the data to your computer for analysis.

If you are using a PC Card recorder, remove the PC Card from the recorder and insert it into the PC Card bay on your computer. When you acquire this data, make sure that the correct PC Card recorder is selected for ECG Data Source.

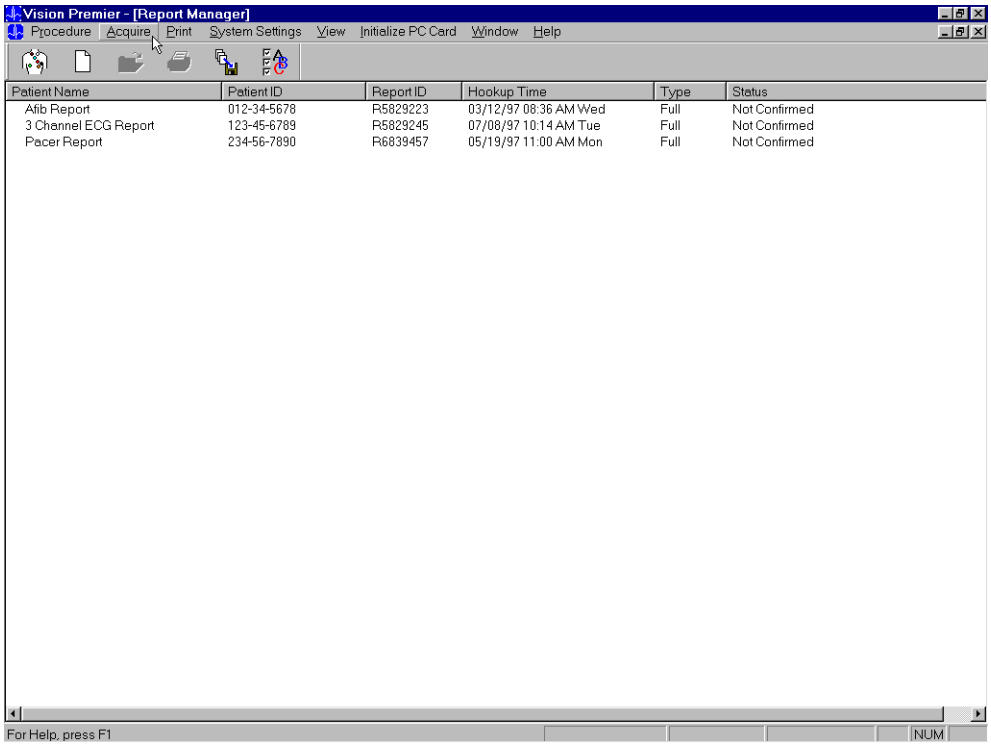
If you are using a cassette tape recorder, remove the tape from the recorder and insert it into the tape reader connected to your computer. When you acquire this data, make sure that the correct tape recorder is selected for ECG Data Source.

To acquire and analyze data:

> **NOTE:** If, at any time, you are unable to proceed to the next step refer to "Maintenance & Troubleshooting" on pg. 14-1.

1. Start the Vision Premier™ program. The ***Report Manager*** window is displayed.

Figure 3-1
Report Manager

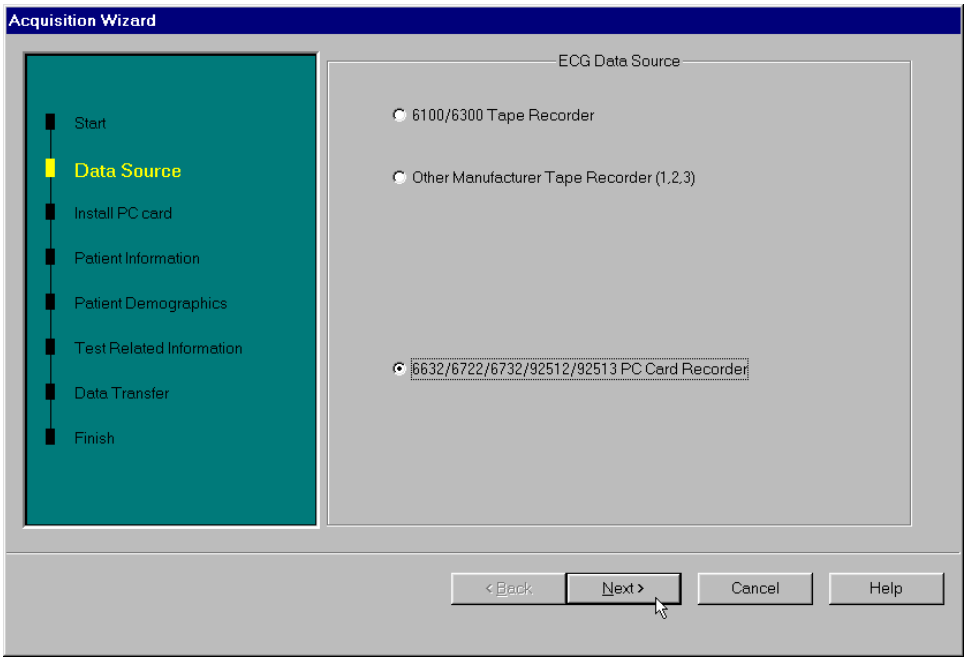


2. Select Acquire from the menu bar or click on the Acquire New Report icon ( ). The Acquisition Wizard is presented to guide you through the steps necessary to acquire the patient record from the recording media.

NOTE: The steps presented in the acquisition wizard are automatically determined by the recorder hardware you have installed. Some of the steps discussed in this manual may not appear on your system. You may skip those steps. The wizard will guide you through the steps that are necessary for your system.

3. The ***ECG Data Source*** screen is displayed.

Figure 3-2
Acquisition Wizard – ECG Data Source

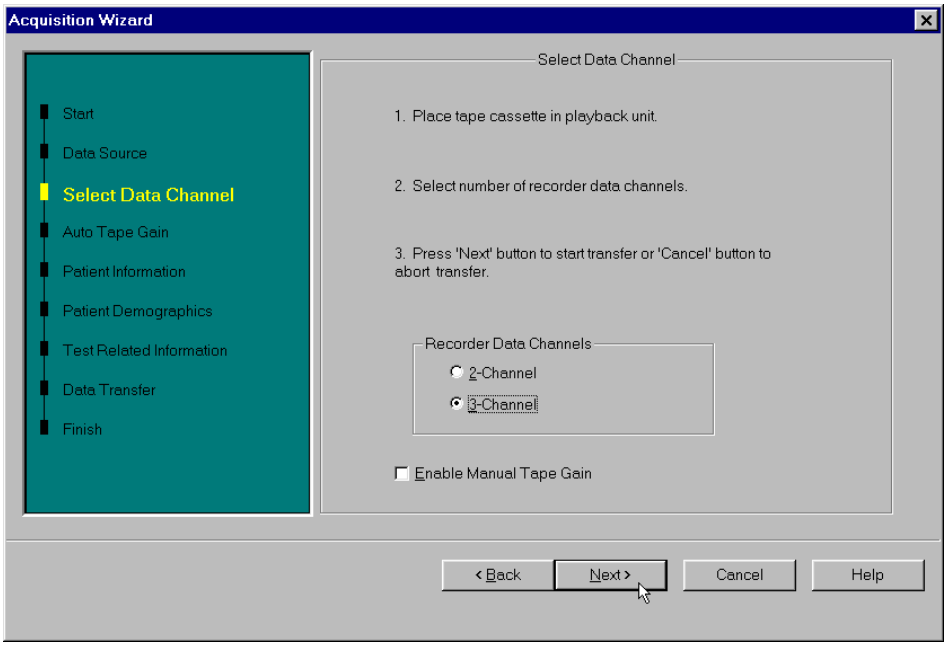


NOTE: The ***Select ECG Data Source*** dialog will not be seen by users that have a PC Card system only. All Tape and Tape - PC Card combination systems will see the Select ECG Data Source dialog box.

4. Select which type of recorder you have used to record the patient's data by clicking the appropriate radio button.
5. Click [Next] to continue. If you selected a tape recorder in step 4, the ***Select Data Channel*** screen is displayed. If you selected a PC Card recorder, skip to step 10.

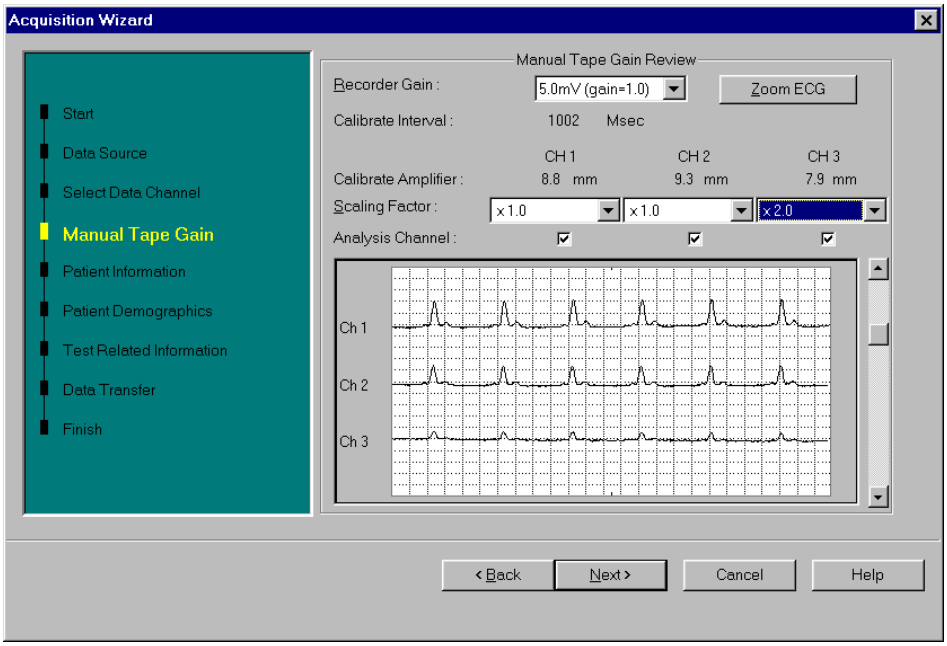
   If you have not yet inserted the cassette or PC Card, you will be prompted to do so at this point.

Figure 3-3
Acquisition Wizard –
Select Data Channel



6. Select the number of data channels you wish to acquire, either 2- or 3-channel. At this point, you have the option of letting the system determine the optimum tape gain settings or setting them yourself. If you wish to allow the system to determine the tape gain settings, ensure that the Enable Manual Tape Gain check box is unchecked and click [Next]. The ***Tape Calibration Data Transfer*** screen is displayed and the system automatically transfers the calibration data from the tape. Proceed to step 10.
7. If you wish to set the tape gain manually, click in the Enable Manual Tape Gain check box and click [Next]. The ***Tape Calibration Data Transfer*** screen is displayed and the system automatically transfers the calibration data from the tape.The ***Manual Tape Gain Review*** window is displayed.

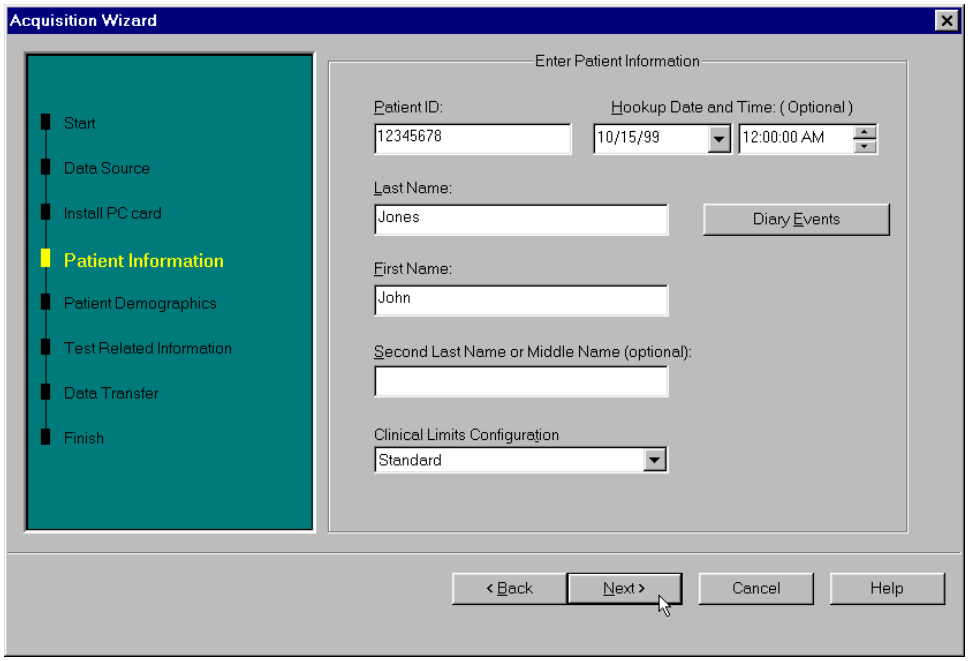
Figure 3-4
Acquisition Wizard –
Manual Tape Gain Review



8. Set the Recorder Gain to the setting that was selected on the recorder during the recording process.
9. Select the desired Scaling Factor for each channel. The data shown in the ECG window is the uncalibrated data from the first hour of the recording. Use this to determine the appropriate scaling factors. When the tape gain settings are as you wish them, click [Next].
10. The ***Enter Patient Information*** screen is displayed.

    NOTE: If patient information was entered during PC Card initialization, then this information will appear automatically in the ***Enter Patient Information*** window. Continue to step 18 on page 3-5.

Figure 3-5
Acquisition Wizard –
Enter Patient Information



NOTE: Although it is possible to enter a total of 50 characters in each name field, Vision Premier™ will display only the first 52 characters of the combined name fields in the ***Report Manager*** window. The name and patient ID may also be truncated to fit on the printouts.

11. Enter the Patient ID (identification number) [32 characters maximum].
12. Click in the Last Name field and enter the patient's Last Name [64 characters maximum].
13. Click in the First Name field and enter the patient's First Name [64 characters maximum].

NOTE: These are the only fields which are required in order to acquire the record from the PC Card or tape. You may skip to step 19, if desired.

14. Click in the Second Last name or Middle Name field and enter the patient's second last name or middle name [64 characters maximum].

15. To apply preset clinical limits to the patient data, select one of the five options from the Clinical Limits Configuration pull down menu. See "Clinical Limits" on pg. 12-4 for information on the Clinical Limits settings.

16. The Hookup Date is automatically filled in with:

- ✔ the date entered during initialization, *or*
- ✔ the business day prior to the current date

Use the patient diary to verify this information. Change the date if necessary.

17. The Hookup Time is automatically filled in with:

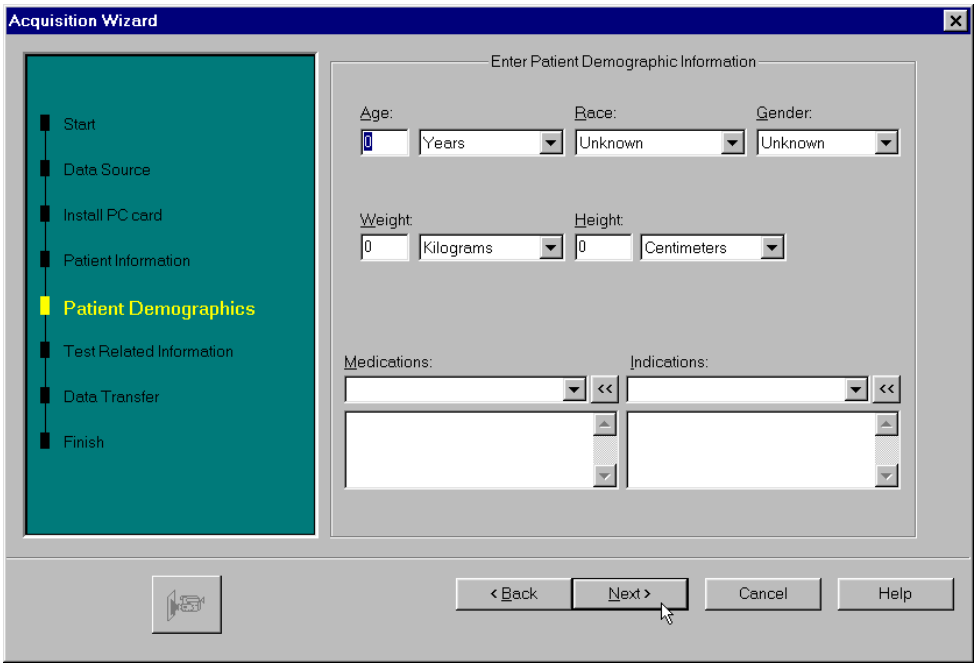
- ✔ the time entered during initialization, *or*
- ✔ the current time

Use the patient diary to verify this information. Change the time if necessary.

18. To add comments to the patient event list or to insert patient diary time and comments, see "Diary Event Entry" on pg. 3-8.

19. Click [Next]. The ***Enter Patient Demographic Information*** screen is displayed.

Figure 3-6
Acquisition Wizard – Enter Patient Demographic Information



NOTE: All of the fields in this screen are optional. You may skip to step 26 if you do not wish to include any of this information in the patient's report.

20. Enter the patient's Age and select the proper age units from the drop down menu.

21. Select the patient's Race from the pull down menu.

22. Select the patient's Gender from the pull down menu.

23. Enter the patient's Height and Weight and select the appropriate units from the pull down menus.

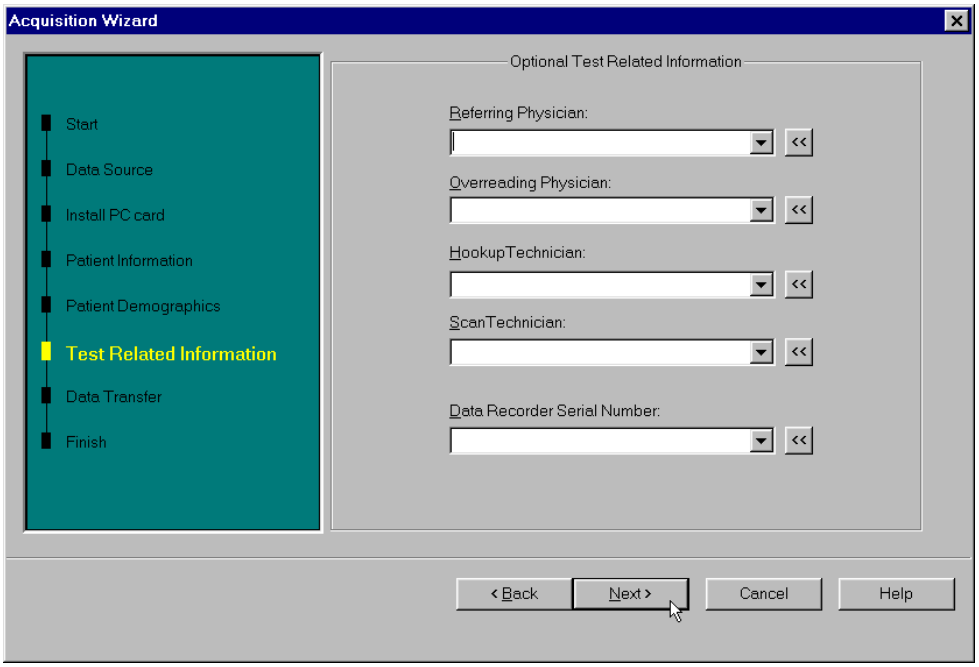
NOTE: The lists that appear in the Medications and Indications fields may be edited. Click on the expand button (<<) and you are presented with a new window where you can add, delete or edit the available selections.

24. Select any Medications that the patient is taking from the pull down menu or, if the medications are not listed, type them in the text entry field.

25. Select any Indications that the patient exhibits from the pull down menu or, if the indications are not listed, type them in the text entry field.

26. Click [Next]. The ***Optional Test Related Information*** screen is displayed.

Figure 3-7
Acquisition Wizard – Optional Test Related Information



NOTE: All of the fields in this screen are optional. You may skip to step 32 if you do not wish to include any of this information on the patient's report.

NOTE: All of the lists that appear in this window may be edited. Click on the expand button (<<) and you are presented with a new window where you can add, delete or edit the available selections.

27. Select the Referring Physician from the pull down menu or, if the physician is not listed, type the physician's name in the text entry field.

28. Select the Overreading Physician from the pull down menu or, if the physician is not listed, type the physician's name in the text entry field.

29. Select the appropriate Hookup Technician from the pull down menu or, if the technician is not listed, type the technician's name in the text entry field.

30. Select the appropriate Scan Technician from the pull down menu or, if the technician is not listed, type the technician's name in the text entry field.

31. Select the Data Recorder Serial Number from the pull down menu or, if the recorder is not listed, type the recorder number in the text entry field.

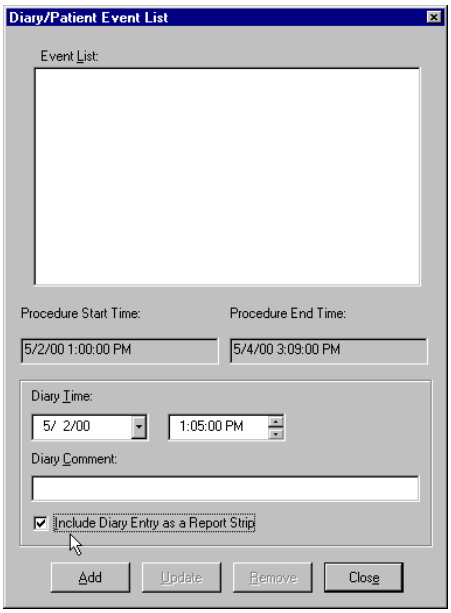
NOTE: If the recorder serial number was entered during recorder initialization, then this information will appear automatically in the ***Optional Test Related Information*** window.

32. Click [Next] when you are finished editing the information in this screen. The record is copied to your computer and analysis is performed.
33. The new record is listed in the ***Report Manager*** window. The complete, unedited report and full disclosure is now ready for you to review, edit and print.

Diary Event Entry

To add comments to the patient event list or to insert patient diary time and comments, click [Diary Events] in the ***Enter Patient Information*** window. The ***Diary/Patient Event List*** window is displayed.

Figure 3-8 Acquisition Wizard – Diary/Patient Event List



Using the patient's diary, enter information as necessary. If you want the diary entries included as a report strip in the final report, ensure this option is checked.

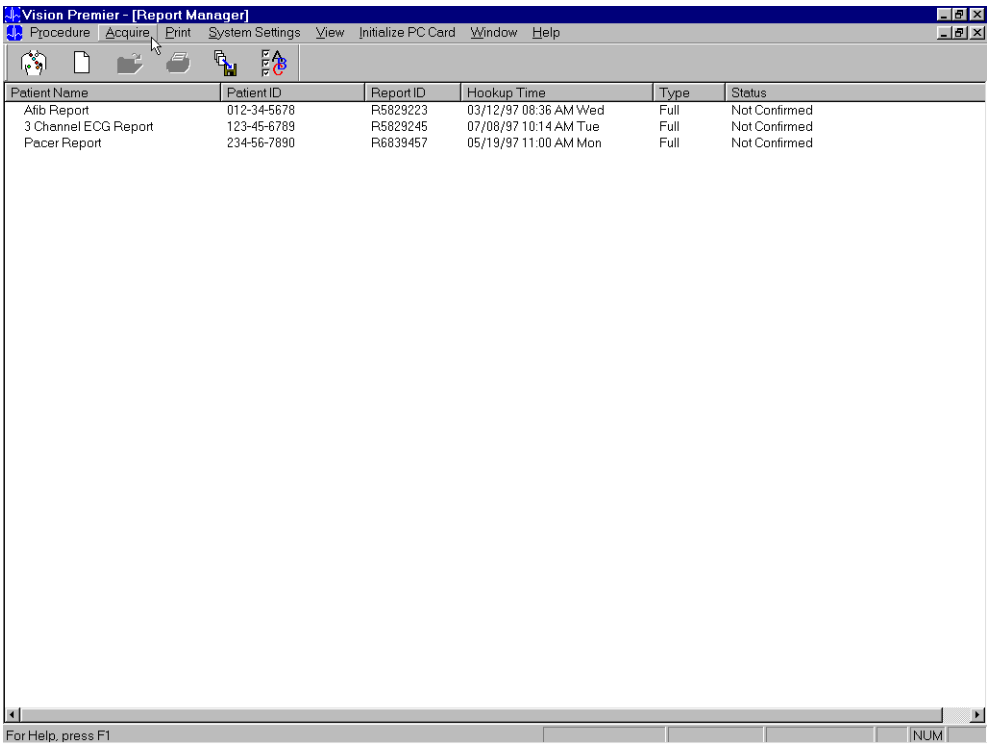
- To enter a diary event, enter the date and time under Diary Time. Use the keyboard to enter information under Diary Comment. Click **Add** to add the entry to the **Event List**. Repeat these steps as necessary to enter all of the diary events.
- To update an entry, select the entry in the Event List. Make changes as necessary in the Diary Time and Diary Comment boxes. Click [Update].
- To remove an entry, select the entry in the Event List and click [Remove].

When you are finished editing, press [Close]. You are returned to the ***Acquisition Wizard-Patient Information*** window.

Chapter 4 *Managing Reports*

When you first start the Vision Premier™ program, the first thing that is displayed is the ***Report Manager*** window.

Figure 4-1
Report Manager



This window is your starting point for accessing and organizing all of your patient records.

Sharing Records over the Network

NOTE: Network sharing features are available only on Vision Premier.

NOTE: In order to share records over the network with other users, you must install multiple licenses of Vision Premier. Additionally, you must configure the system for network use; for more information, see the Vision Series Setup Guide.

If another user on the network opens a record, then Vision Premier™ locks the record to everyone but the user until the user closes the record. The record is unavailable to other users and shows a status of Opened Review/Edit in the ***Report Manager*** window.

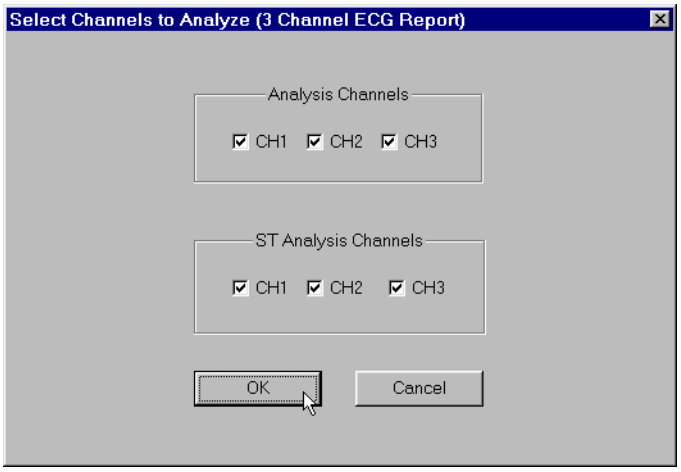
Sorting Patient Reports

At the top of the ***Report Manager*** window, below the toolbar, is a special kind of menu. This menu displays titles for the columns of information which are displayed for each report such as Patient ID. Click on a title in this menu to sort all the displayed records according to the information in that column into descending or ascending order.

Analyzing Patient Records

To eliminate any editing that may have been done on a patient's report and generate a new report based on the original data, you may re-analyze the report. To re-analyze a patient's record, highlight the record and click on Procedure in the menu bar then select Analyze from the pull down menu. The Select Channels to Analyze window is displayed.

Figure 4-2
Select Channels to Analyze



Select each of the channels you wish to re-analyze, and click [OK].

Changing Reports to be Displayed

You may determine which types of reports are displayed in the ***Report Manager*** window. The options are:

- ✔ All Reports
- ✔ Full Disclosure Reports only
- ✔ Summary Reports only
- ✔ Nonconfirmed Reports only
- ✔ Confirmed Reports only

These options make it easier for you to select the reports you wish to work with during a particular session.

Click on View in the menu bar and select the type of reports you wish to see displayed. The Refresh option updates the screen.

Tracking Open Windows

Another item in the ***Report Manager*** menu bar is the Window option. Select from the pull down menu under Window to manage how you want to view open windows. The Cascade option allows windows to appear over one another while the Tile option makes every window fit so that no window is obscured by any other.

Each open window is listed at the bottom of the pull down menu. The window which is currently active is indicated by a check mark.

Backup and Restore of Reports

The Vision Premier™ system allows you to backup or store your patient records to any digital storage device that is accessible to your computer. You can then restore those reports to your hard drive if you need to review or print them. Click on the Archive icon ( ) in the toolbar. Select Backup or Restore from the options presented.

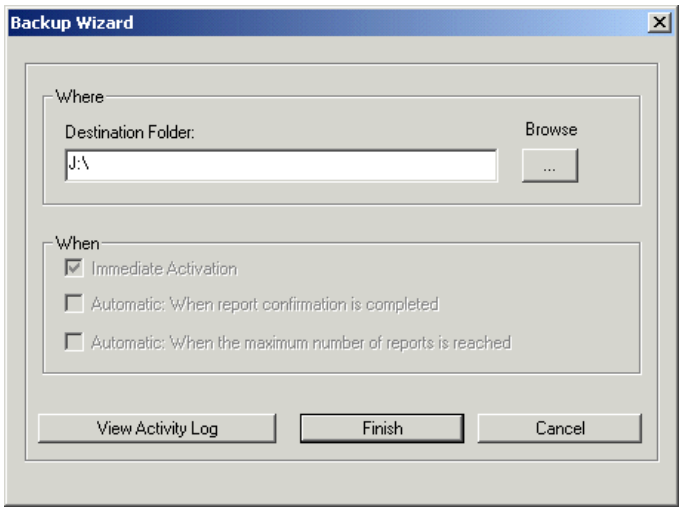
NOTE: The Full Disclosure, Final Report and summary reports may be archived.

Backup Reports

This option allows you to backup a report to a local, network, optical, CDR or CDRW drive.

1. Select the Backup option and the ***Backup Wizard*** window is displayed.

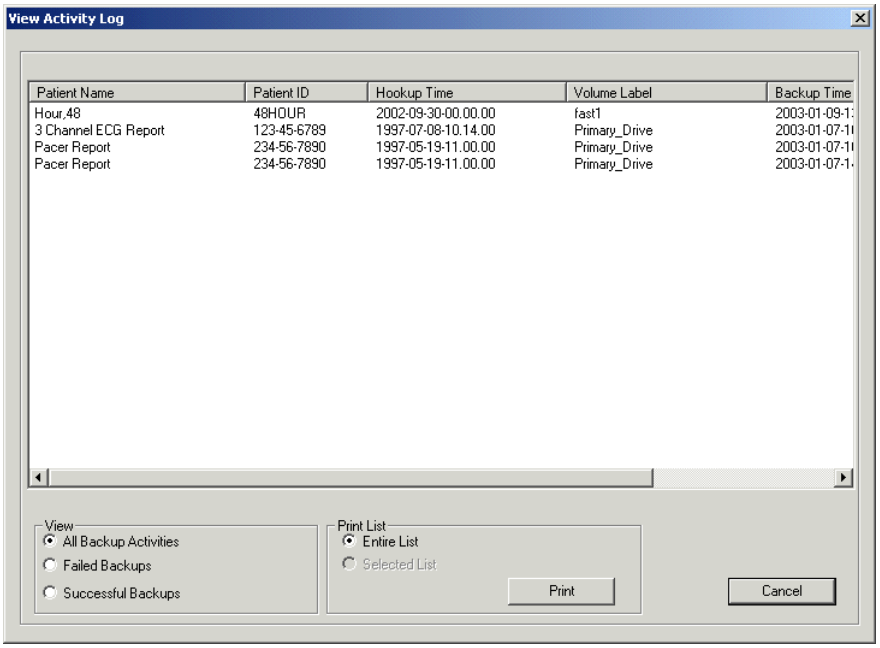
Figure 4-3
Backup Wizard



2. Under **Where**, enter the destination folder where you want the backup file to go. If you want to change the destination folder, click the [Browse] button to locate and select the new drive or folder you wish to use.
3. Click the [Finish] button to start the backup process. If an error occurs during the backup process, a message is displayed in the ***Report Manager – Status*** column.

You may also select the [View Activity Log] button on the ***Backup Wizard*** window to display the ***View Activity Log*** window.

Figure 4-4
View Activity Log



This window automatically sorts reports according to the time of backup (the last report backed up is at the top of the list). The list can also be sorted into ascending or descending order by column title, such as Patient ID.

In the ***View Activity Log*** window, two additional group boxes are shown: the ***View*** group box and the ***Print List*** group box. Selecting a radio button in the ***View*** group box will automatically display the corresponding backup reports for the view selected. Selecting a radio button in the ***Print List*** group box will select the Entire List of reports or the Selected List of highlighted reports for printing. Click on a report to highlight it. To select more than one report, press and hold the CTRL key while clicking on the reports.

> **NOTE:** The Selected List option becomes active after a report is highlighted.

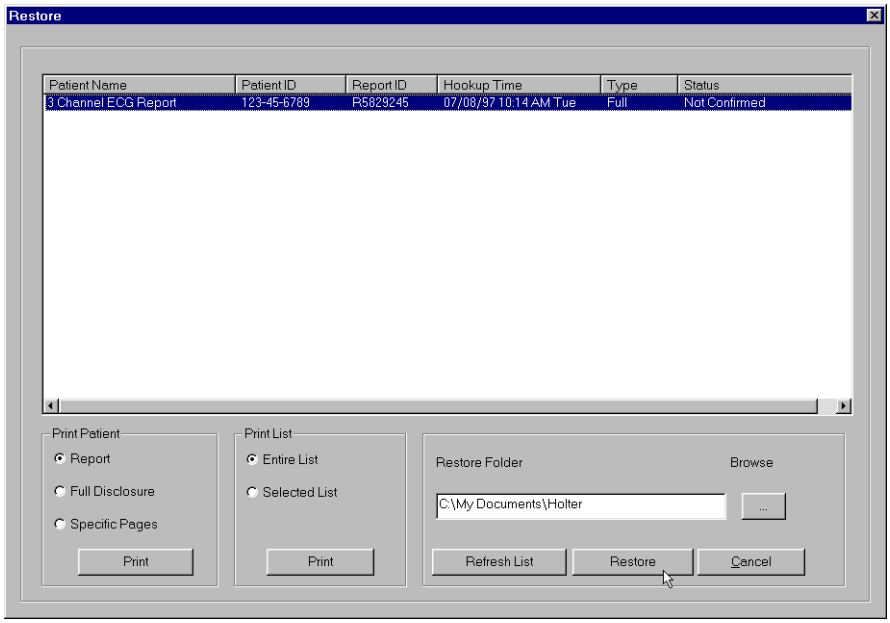
After making your selections from the ***View*** and ***Print List*** group boxes, click the [Print] button in the ***Print List*** group box to print your selection(s) from the ***View Activity Log*** window to your printer. To cancel any actions in the ***View Activity Log*** window and return to the ***Backup Wizard*** window click the [Cancel] button.

Restore Reports

This option allows you to restore a report from a local, network, optical, CDR or CDRW drive.

1. Select the Restore option and the ***Restore*** window is displayed.

Figure 4-5 Restore



2. Enter the ***Restore Folder*** where you want to get the report from. If you want to change the ***Restore Folder***, click the [Browse] button to locate and select the new drive or folder you wish to use. The records available in the location you have selected will be listed.
3. If a folder is manually selected, click the [Refresh List] button to update the list according to what reports are available for restoring. Select the report to be restored by clicking once on it and tagging it. The ***Print Patient*** group box and the ***Print List*** group box options are now available. To select more than one report, press and hold the CTRL key while clicking on the reports.

The ***Print Patient*** group box allows you to print specific components of an individual report without actually opening or restoring the report. Select the Report option to print the entire Final Report at the time the report was active in the system. Select the Full Disclosure option to print the entire procedure or portions of patient data as defined in the ***System Settings*** window (see "Print" on pg. 12-2.) Select the Specific Pages option to print only the Final Report pages that you select. A window similar to the ***System Settings*** window (see"Print" on pg. 12-2) is displayed allowing you to make selections that affect only the current printout.

The ***Print List*** group box allows you to print the Entire List of restorable reports or the Selected List of tagged reports as shown in the ***Restore*** window. Printing this list would be recommended in order to have a printed copy of a patient reports backed up on this logical drive.

4. Click the [Restore] button to start the restore process or click the [Cancel] button if you do not want to restore a report at this time.

Summarizing Reports

Once a Holter report has been reviewed by a doctor, and further actions have been taken (if necessary), full disclosure data may not need to be saved on Vision Premier™ any longer. Full disclosure reports can be converted to summary reports using the Summarize procedure. When a report is summarized, full disclosure data is discarded. The summary reports consists of a cover page, VE tabular, SVE tabular, pacer tabular, narrative, graphic summary, ST summary and strips.

Summary reports require very little space compared to full reports, and therefore potentially can be saved longer than full reports (for more information, see "Maximum Reports" on pg. 12-7).

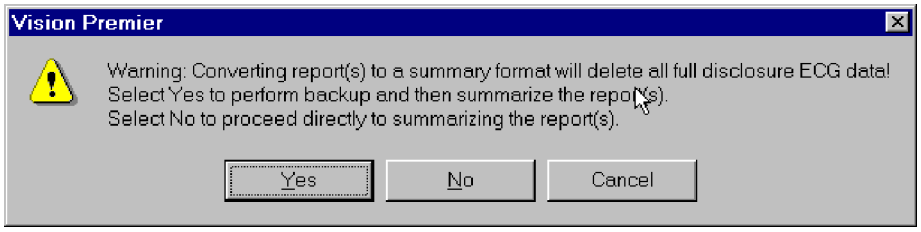
To convert a full disclosure report to a summary report:

1. Highlight the desired record in the ***Report Manager*** window.

   NOTE: To select more than one report, hold down the Control key.

2. Select Procedure from the menu bar.
3. From the pull down menu, select Summarize.
4. The following message box appears.

Figure 4-6
Summarize warning



   To backup the full report before proceeding, select [Yes]. The ***Backup Wizard*** window is displayed. Enter the destination folder and select [Finish].

   To proceed without backing up, select [No].

   NOTE: Full disclosure data will be lost if the full report is not backed up prior to summarizing.

   To exit without performing any action, select [Cancel].

Once a report has been converted a summary report, the Type as shown in the ***Report Manager*** window changes to Summary.

Chapter 5 *Reviewing the Report*

The Vision Premier™ system provides a comprehensive and detailed report of a patient's ambulatory cardiac procedure.

> **NOTICE:** Computer assisted interpretation is a valuable tool when used properly. However, no automated interpretation is completely reliable and interpretations should be reviewed by a qualified physician before treatment, or non-treatment, of any patient.

Beat Classification

During analysis, the Vision Premier™ Holter analysis system uses a technique known as feature extraction to group, based on their features, the individual QRS complexes into forms. These formal and heuristic features include QRS morphology, QRS width, QRS absolute area, QRS offset, QRS peak-to-peak amplitude and prematurity.

After the individual QRS complexes have been consolidated into forms, the forms are classified into one of the following categories: Normal (N), Ventricular (V), Paced (P), Other (?) or Artifact (A). Paced beats are identified only if you are using the optional pacer software.

Identification of ventricular and supraventricular arrhythmias takes place. These are then classified as runs, couplets, isolated or SV episodes.

Rate-dependent arrhythmias, tachycardia and bradycardia, are calculated on the basis of the RR intervals measured in an eight-beat sliding window.

Pauses are identified when an RR interval exceeds preset criteria.

ST changes, both negative (depression) and positive (elevation), that satisfy the criteria for amplitude, duration, and separation from prior episodes are identified as ST episodes.

Prior to printing the report, the classification of all arrhythmia and ischemic episodes can be reviewed and edited.

> **NOTE:** The Vision Premier™ system locks out the first five minutes of ECG data which is used for calibration. These beats are labeled U (Uneditable) in graphic displays.

Viewing and Editing

There are several ways to advance through the pages of the final report; use the method that is most comfortable for you:

- ✔ Select View in the Menu bar. From the pull down menu, select the page you wish to view.
- ✔ Press PG↑ / PG↓.
- ✔ Click on the Next/Previous page icons (←/→)to move forward or back through the pages.

The Holter data and/or analysis information contained in some of the report pages is editable. If the information on such a page has been edited, then the lower left corner of the window will show * **Modified by user**. Refer to the graphic under "Narrative Summary" on pg. 5-6 for an example.

> **NOTE:** The * **Modified by user** message appears only on the page that has been edited, and is limited to the following pages only: Narrative Summary, Ventricular Tabular, Supraventricular Tabular, Pacer Tabular, and ST Tabular.

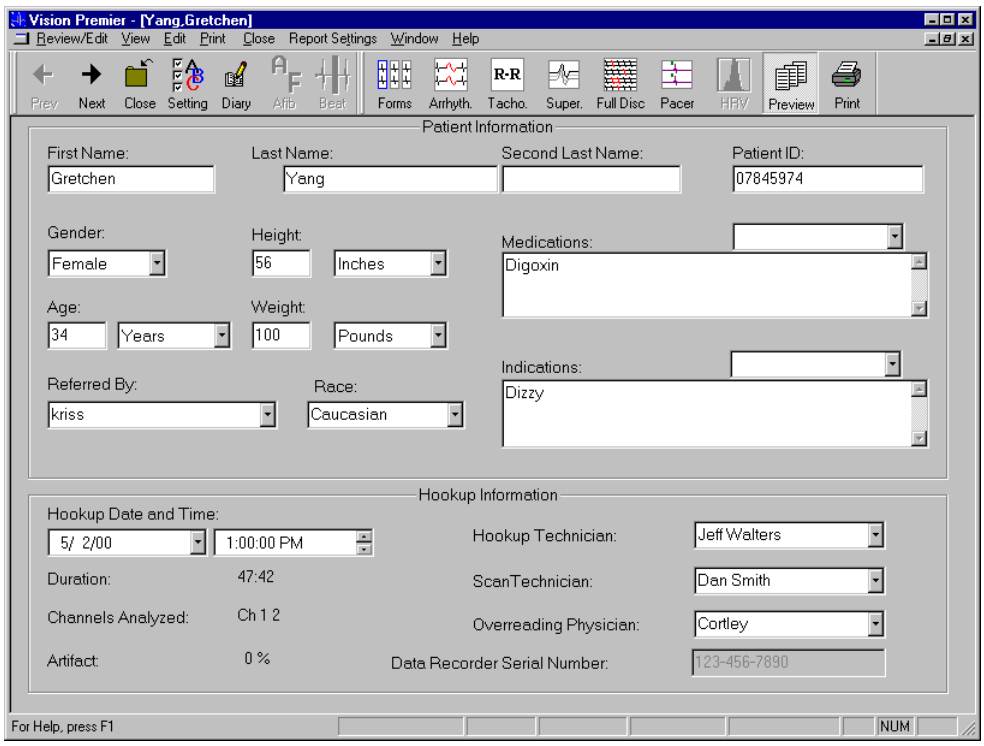
Following is a description of the pages that can be selectively included in the report.

Cover Page

Start from the ***Report Manager*** window. Double click the record you wish to review or edit. The ***Patient Information*** window is displayed. This is the first page of the Final Report Cover Page.

Patient Information

Figure 5-1
Patient Information

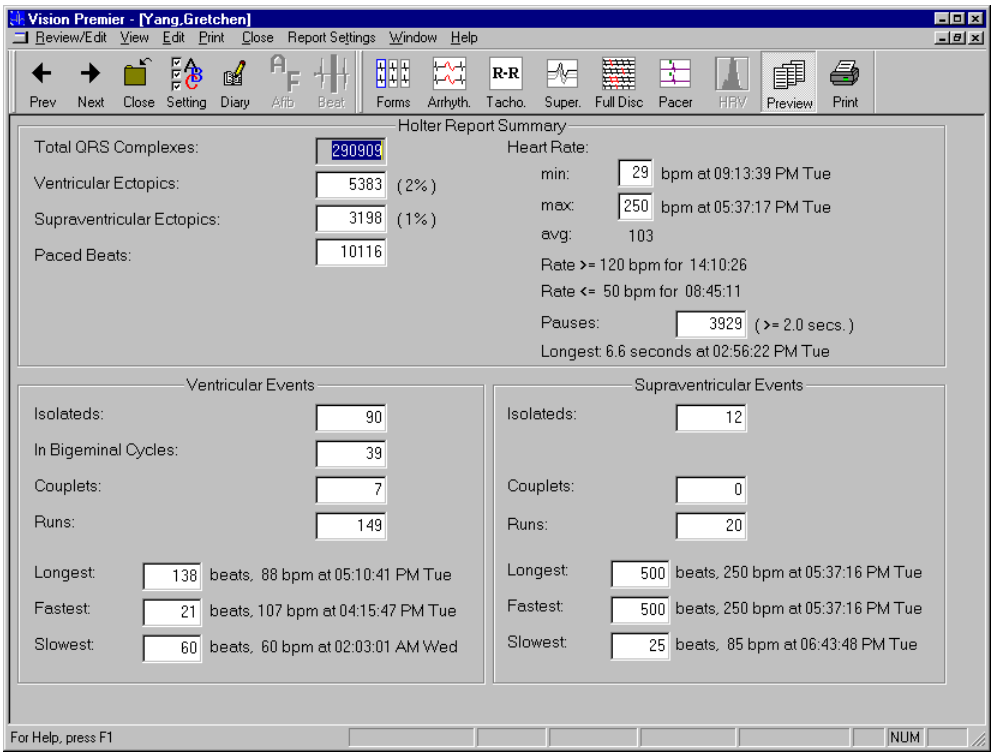


This window includes the patient demographics, medications and clinical indications. Enter the appropriate information using the keyboard.

> **NOTE:** The entries for hookup time, recording duration and channels analyzed are entered during acquisition. You should verify that this information is correct.

Holter Report Summary

Figure 5-2
Holter Report Summary



This section draws the physician's attention to highest and lowest heart rate, total number of QRS, ventricular and supraventricular beats, severity of pauses and the time of occurrence, duration and rate of the longest, fastest, and slowest runs - both ventricular and supraventricular.

Any area that can be highlighted with the cursor can be edited. Before editing, however, you should be aware of the following:

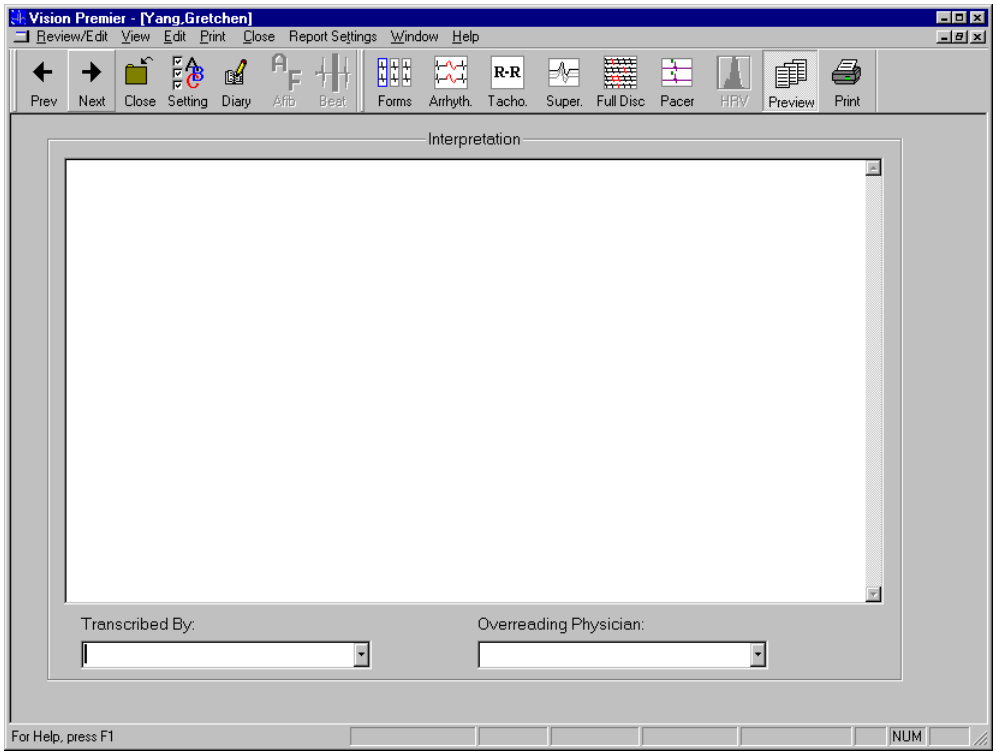
- This is the only place that Bigeminals are reported.
- Heart Rate (minimum and maximum) values must be between 0 and 250.
- The only change that you can make to the rest of the values displayed in this window is to change a value to zero. You can do this if you disagree with the calculated value and wish to have nothing printed on the Final Report. To edit these values to something besides zero, you should edit forms and arrhythmias so that the Vision Premier™ system recalculates the results.

  NOTE: Paced beats can be edited on the pace tabular summary page.

  NOTE: The number of isolated ventricular beats indicated in the Summary section of the cover page is different from that indicated in the Review Arrhythmias display. This is because on the cover page every ventricular ectopic on the record is counted, however, in the Review Arrhythmias display, the last ventricular ectopic of every bigeminal cycle is not displayed.

Interpretation

Figure 5-3
Interpretation Page



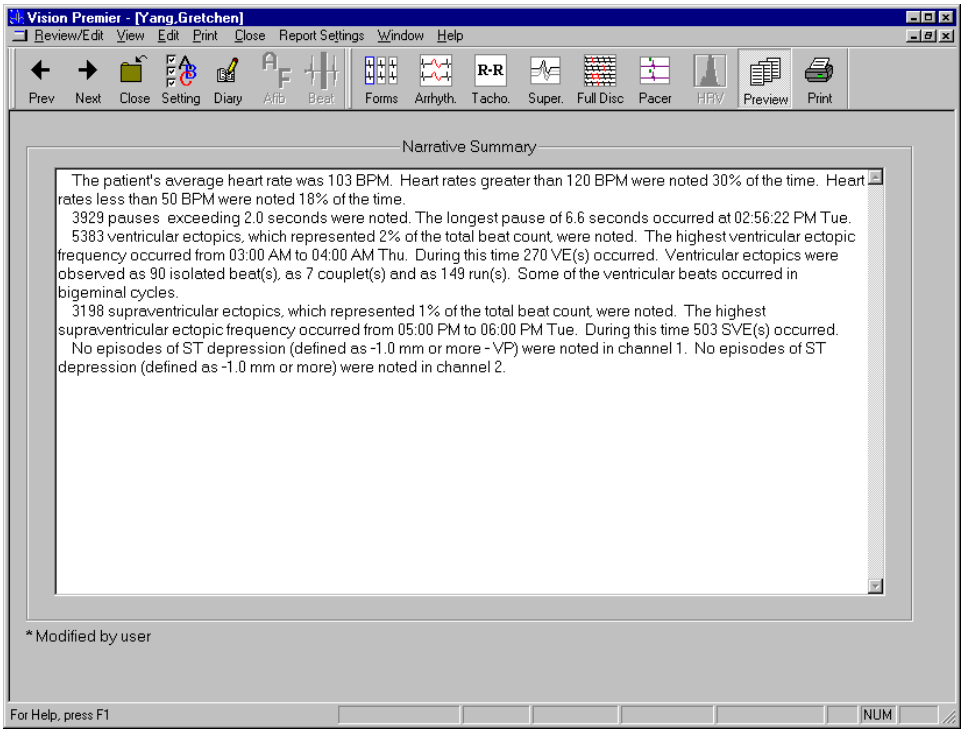
This section provides a place for the reviewing physician to type in the interpretation. Blank lines are omitted in order to save space on the printouts.

If you enter a name (or select one from the drop down menu) in the Transcribed By and Overreading Physician fields, the record report status will be changed to "Confirmed."

When the Cover Page is printed, there is a place for the reviewing physician to sign and date the interpretation.

Narrative Summary

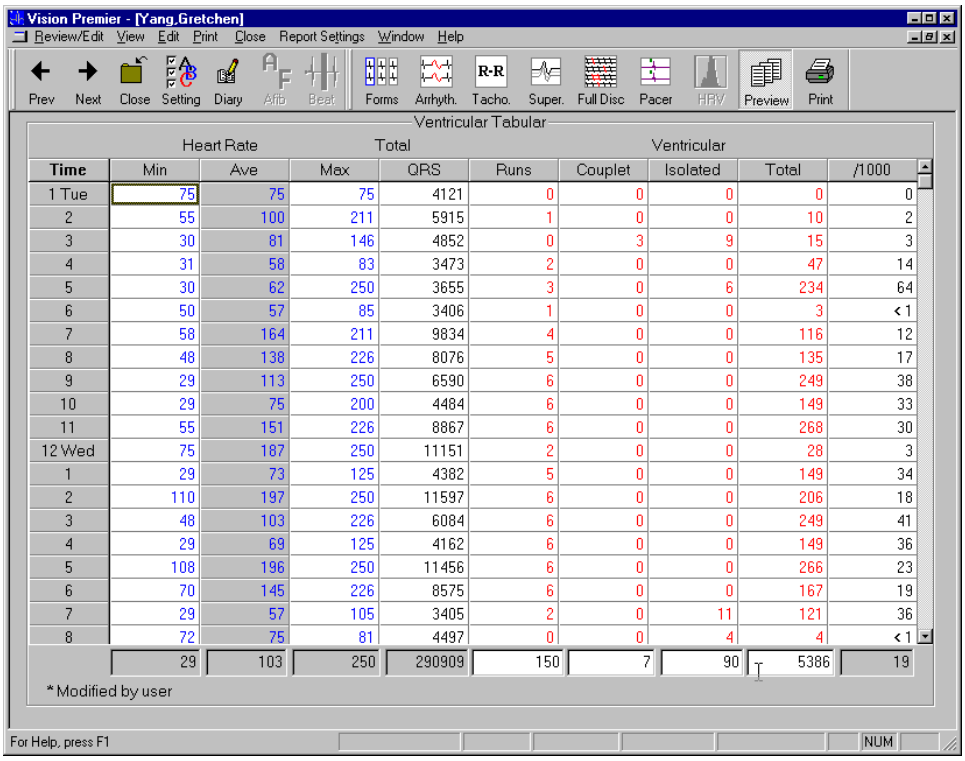
Figure 5-4
Narrative Summary



This page presents a concise statement of the results in an easy-to-read narrative style. It can be used as a preliminary guide for the physician's review of the report or be included in the report as the physician's interpretation.

Tabular Summary

Figure 5-5
Ventricular Tabular Summary



The Tabular Summary pages provide an hourly summary of the results. Variations in heart rate or frequency of arrhythmias during periods of activity or sleep can be easily identified.

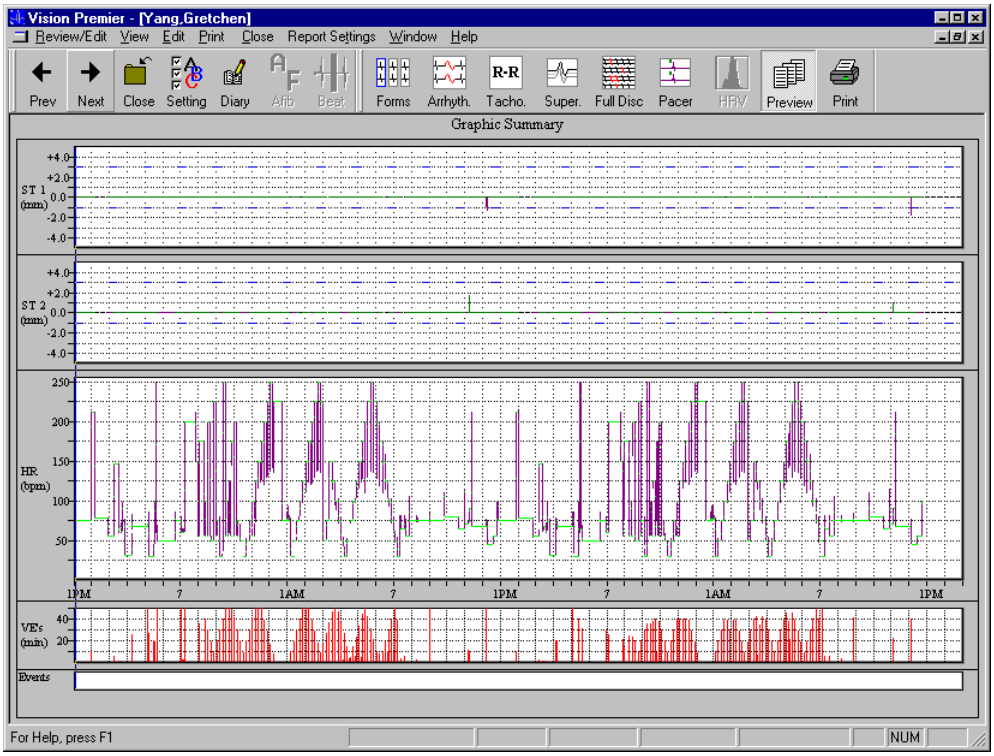
1. Use the arrow keys to move through the columns and rows of each table.

   You may edit any areas that can be highlighted by the cursor, however, if you change the quantity in the Total QRS column, even inadvertently, the system requires that it be changed to 0. You can do this if you disagree with the calculated value and wish to have nothing printed on the Final Report. To edit these values to something besides zero, you should edit forms and arrhythmias so that the Vision Premier™ system recalculates the results.

2. After reviewing the Ventricular Tabular summary, advance to the Supraventricular Tabular screen. This screen is similar to the ***Ventricular Tabular*** screen.

Graphic Summary

Figure 5-6
Graphic Summary



This display shows trends in ST level, heart rate and ventricular frequency for a 24-hour period.

Average ST level is graphed for each channel with 1-minute resolution.

Breaks in the graph indicate that ST measurements were interrupted because of ectopics, wide QRSs or excessive noise/artifacts.

Maximum, average, and minimum heart rates are graphed with 1-minute resolution. Note that the time and rate of maximum and minimum heart rates are also on the report cover page and are included automatically in the selected ECG strips.

Frequency of ventricular beats is graphed with 1-minute resolution.

Tic marks (|) denoting the times at which the patient pressed the event button on the recorder are printed below the ectopic ventricular trends.

The colors on the graphic summary ST level display allow for easy location of information: ST elevations are in green; depressions are in magenta.

The HR graph is divided into two colors: green indicates the average; magenta indicates the high and low rate for each 1-minute interval.

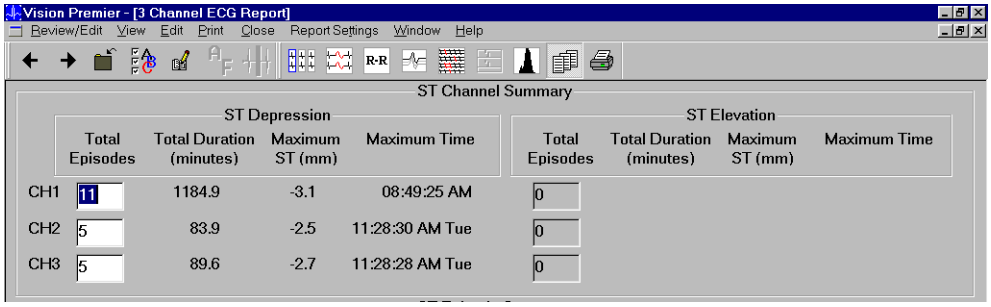
ST Summary

This page provides a detailed summary of all ST episodes that satisfy the clinical criteria for amplitude, duration and separation. It is divided into two sections.

NOTE: The printout of the ST Episode Summary will include a subset of all ST episodes displayed.

ST Channel Summary

Figure 5-7
ST Channel Summary

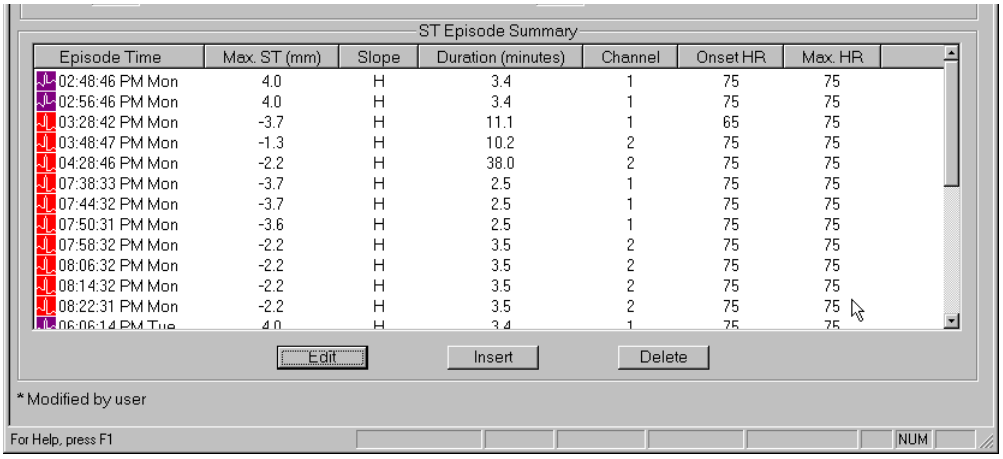


The ST Channel Summary provides:

- The number of episodes of depression or elevation.
- The duration of all episodes.
- The time and maximum depression/elevation of the episodes for each channel of data.

ST Episode Summary

Figure 5-8
ST Episode Summary



The ST Episode Summary provides the following information for each significant episode:

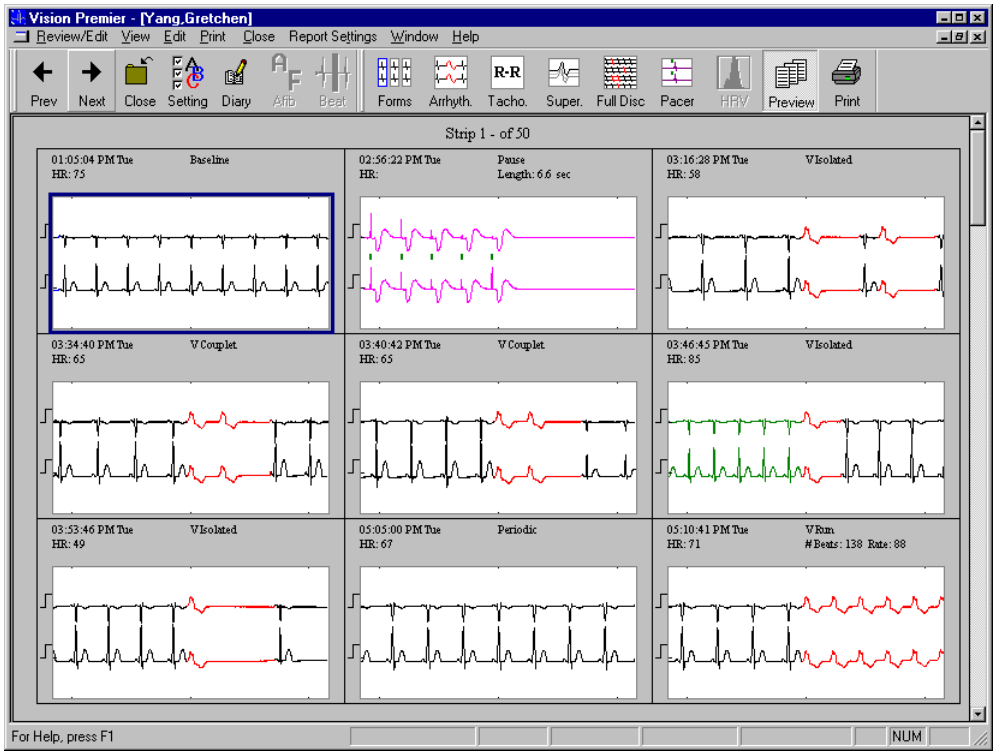
- Onset time and date
- Peak ST change (identified as elevation or depression)
- Slope (downsloping, upsloping or horizontal)
- Duration
- Channel
- Heart rate at onset
- Heart rate at maximum ST change

Each entry listed may be edited, inserted into the Report Strips or deleted.

1. Click the episode you wish to review or edit. The episode becomes highlighted.
2. To edit an episode, click [Edit] at the bottom of the screen. The ***ST Episode Edit*** window is displayed.
3. When all changes have been made, click [OK] to return to the ***ST Summary*** window.
4. To insert an episode into the Report Strips, click [Insert] at the bottom of the screen. The ***ST Episode Edit*** window is displayed.
5. Verify that all the information is correct and click [OK].
6. To delete an episode, click [Delete]. The episode is removed from the list.

Report Strips

Figure 5-9
Report Strips



The final report pages show some of the strips selected by the system to represent the arrhythmias noted in the report.

Each ECG strip shows the designation of the strip, the time and the heart rate. For some arrhythmias (such as runs, pauses and bigeminy) additional information is also included.

For clarity of presentation, the arrhythmia of interest is centered in the strip or, as in the case of runs, tachycardia, bradycardia, bigeminy or pauses, the onset of the arrhythmia is centered.

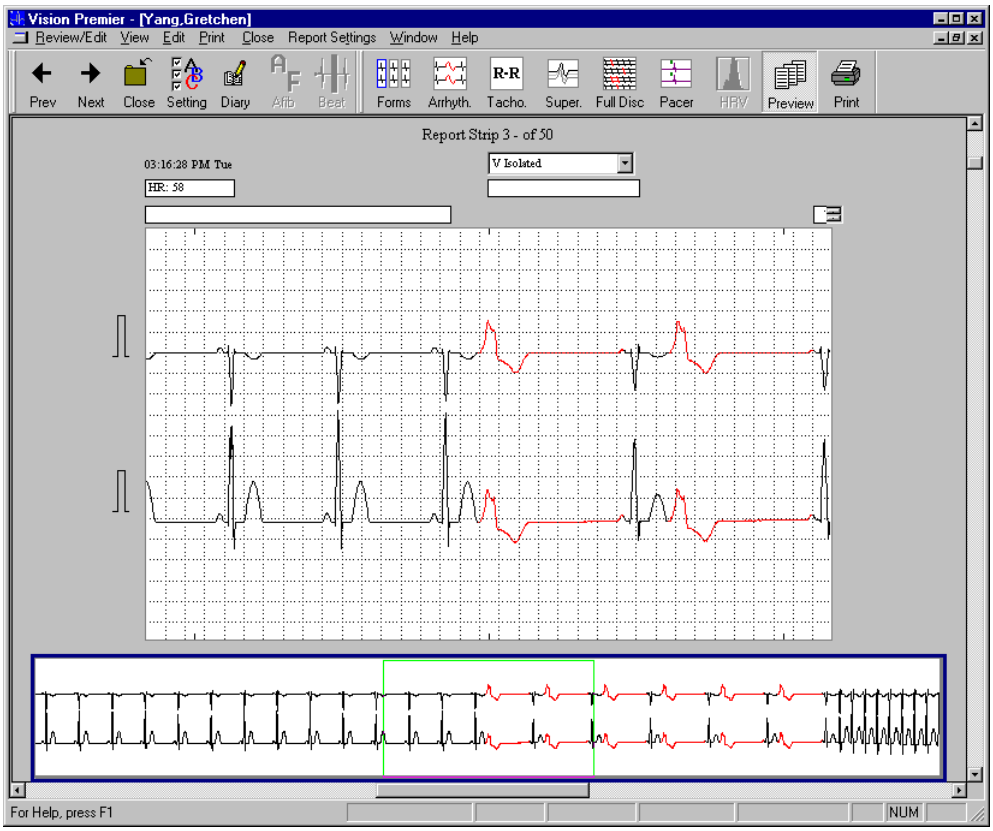
The ECG strips will vary from report to report depending upon system configuration and the data being analyzed. The strips are presented either by time or by category, depending on the report configuration. If they are grouped by time, the strips are printed in chronological order starting at the beginning of the recording. If they are grouped by category, all strips of the same type (isolated, couplets, runs, etc.) are printed together.

To review the remaining report strips, press PG↓ or click in the scroll bar located on the right side of the window. The strips are displayed one after another until the last strip.

The Report Strips may be edited and deleted.

1. To edit a Report Strip, click on the strip to highlight it and press ENTER. A window similar to a diagnostic strip is displayed.

Figure 5-10
Report Strip editing



2. You may edit any of the fields which can be highlighted by the cursor. You can also select a strip label from the drop down menu.
3. When you have finished editing the report strip, press ESC.
4. To delete a Report Strip, click on the strip, in the Report Strip view, to highlight it and press the DEL key.

Chapter 6 *Reviewing & Editing Forms*

The Vision Premier™ system uses a sophisticated algorithm to detect, measure and classify QRS complexes as types of forms.

A form is a group of beats that have similar characteristics. Forms are broken down into five different categories: Normal, Ventricular, Other, Paced and Artifact.

- Normal forms (N) contain normal beats and SVE beats.
- Ventricular forms (V) contain ventricular, fusion, escape and idioventricular beats.
- The Other forms (?) contain questionable normal beats that the system could not identify with 100% confidence. They are placed here for review and editing by you.
- Paced forms (P) contain beats that were generated by a pacemaker (detected only when the pacer analysis software option is installed or when manually labelled by you).
- Artifact forms (X) contain all detected events that were determined to be noise or artifact. T-waves, P-waves and noise are examples of Artifact forms and beats.

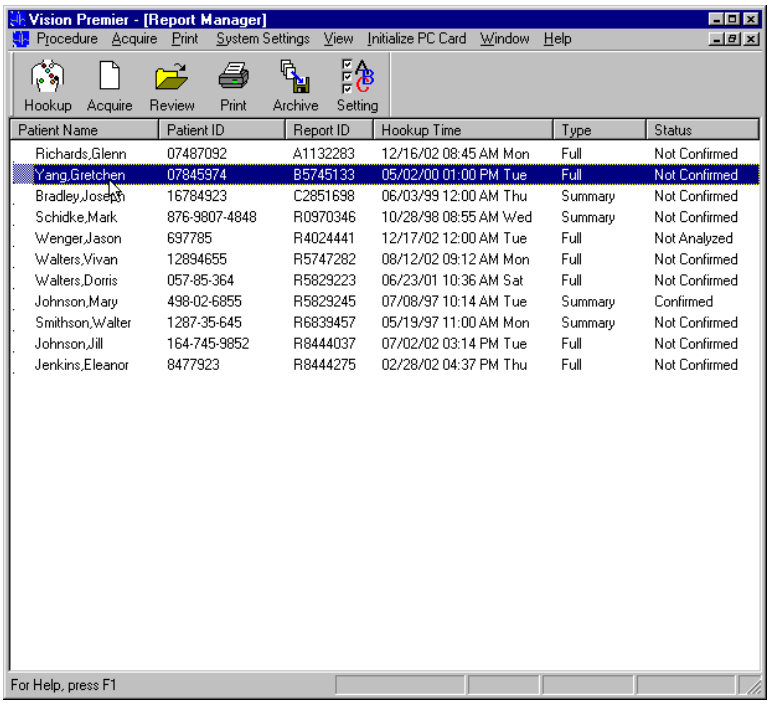
The Vision Premier™ system offers many powerful editing capabilities that allow you to change the system's original classification. These editing capabilities allow you to override the form or beat classification assigned by the system.

When form editing has been completed, the Vision Premier™ system automatically recompiles the report and incorporates your changes into the final results. All aspects of the report are affected; hourly totals and beat totals. Even strips selected for the report may be changed.

Reviewing Forms

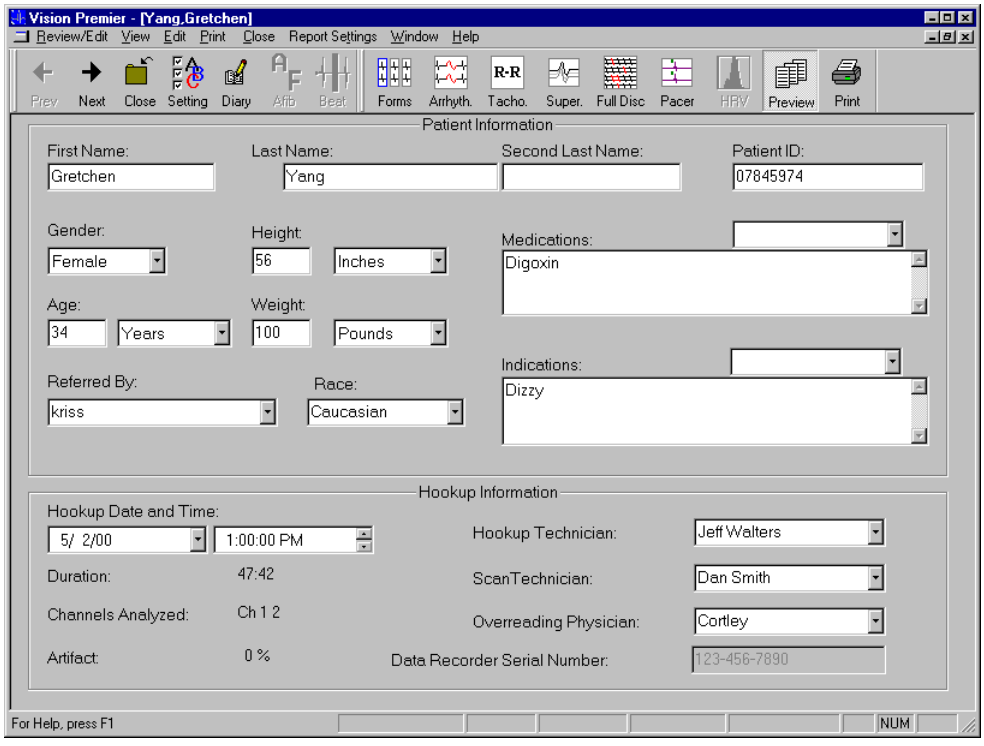
1. Start from the ***Report Manager*** window.

Figure 6-1
Report Manager



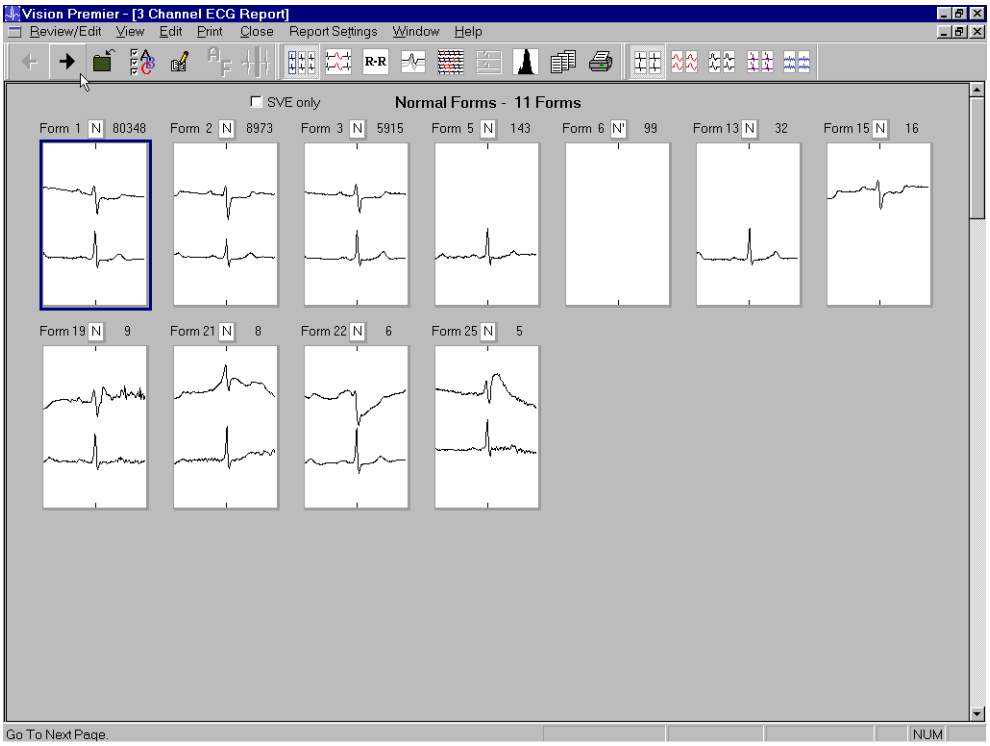
2. Double click the record you wish to review or edit. The ***Patient Information*** window is displayed.

Figure 6-2
Patient Information



3. Verify that the information displayed in the window is correct.
4. Click the Forms icon ( )in the toolbar. The ***Normal Category*** forms window is displayed.

Figure 6-3
Normal Forms



NOTE: There are several ways to advance through the various sets of forms: 1.) Click on the icon for the classification of forms you wish to view. 2.) Select View in the Menu bar. From the pull down menu, select the classification of forms you wish to view. 3.) Press PG↑ / PG↓ or click on the Next/Previous page icons (←/→) to move forward or back through the pages. Use the method that is most comfortable for you.

NOTE: If there are more than 21 forms in the category, more than one screen may be displayed for that category and you will need to press PG↓ to move to the next set of forms.

The Form Display

The forms are displayed in groups of up to 21 per screen. Each screen gives the following information:

- ✔ Category
- ✔ Number of forms in the category
- ✔ Each form's number and population
- ✔ Letter used to designate the form (for example, N for Normal)

Form Numbers

Form numbers are assigned based on the number of beats in the form (and does not depend on the beat category). Form 1 always has the largest number of beats.

Prime Forms

While reviewing forms you may notice that one form in a category does not display any waveform in the viewing window. This indicates that this is the prime form. The prime forms are also indicated by a small tic mark next to the form designation (N').

The beats grouped in the prime form do not fit any other form. At least five beats that share the same morphology are required to create a form. If there are not enough beats to create a form, the beats are placed in the prime form for that category.

Displayed Channels

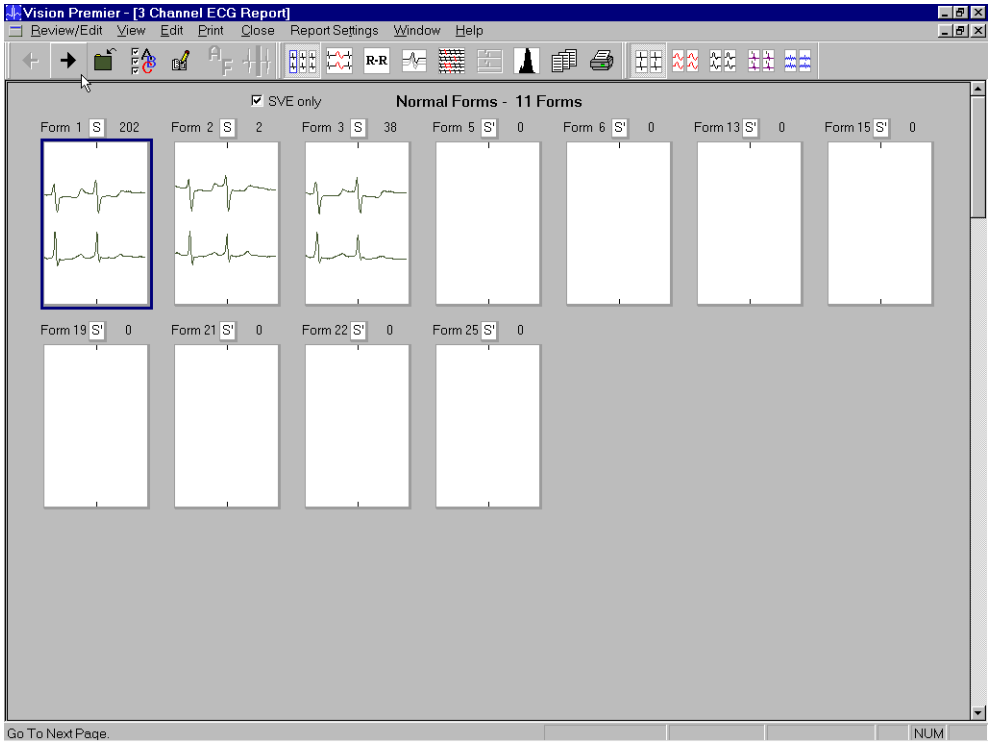
A form that does not display a waveform for channel 1 or channel 2, indicates that those beats within that group may have had a low amplitude signal in the other channel or artifact. Typically, the unused channel contains data with too much artifact or with a wandering baseline.

SVE Only

The SVE Only checkbox appears on the Normal Forms display. When this box is checked, if there are any SVE beats within the currently highlighted form, a representative SVE beat and the count of SVE beats within that form are displayed.

Using the SVE Only option provides a more detailed view of the SVE morphology. It provides a useful tool to edit false positives, i.e. artifact, from the report. SVE false positives are typically recorded as single channel forms.

Figure 6-4
Normal Forms – SVE Only



Editing Forms

While reviewing forms, the first form is highlighted. The highlight cursor can be moved with the arrow keys or by clicking once on the desired form. The highlighted form is the one that can be edited.

To edit a form designation (and the designation of all the beats in that form):

1. Highlight the desired form.
2. Click Edit in the menu bar or click on the form with the right mouse button and select the desired form label from the list. The form is automatically moved to the correct category and the label is changed. All the beats included in the form are relabeled.

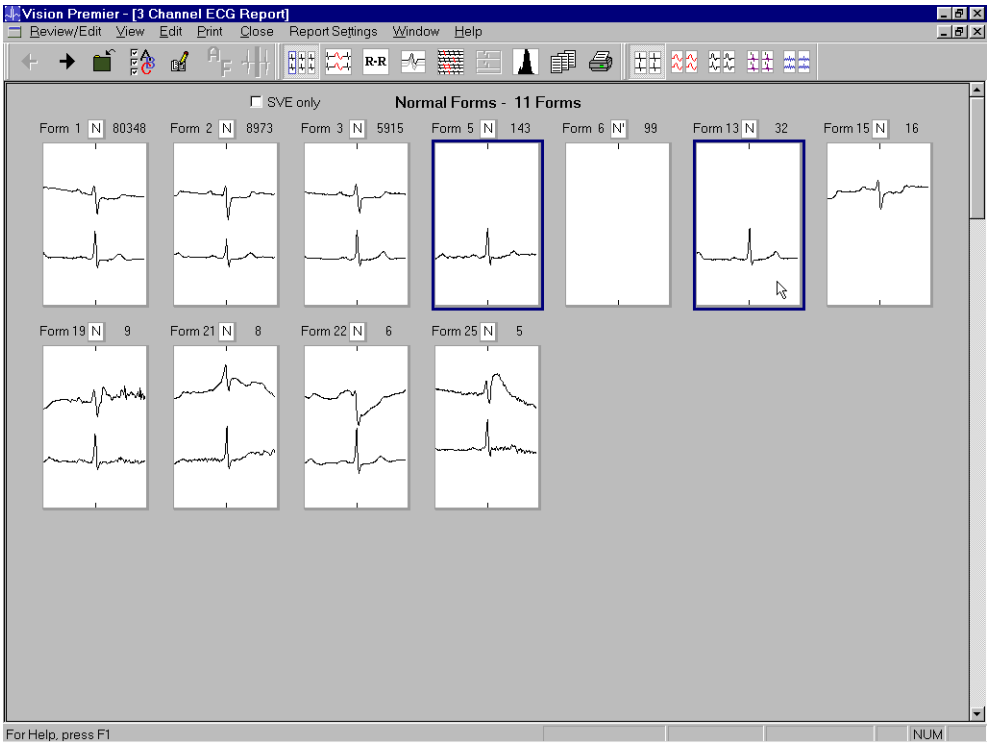
Merging Forms

If there are two or more forms containing the same type of beats, they may be merged to create one larger form. Merging does not affect data analysis.

To merge two forms:

1. Highlight the forms you wish to merge by holding down CTRL while clicking on each form.

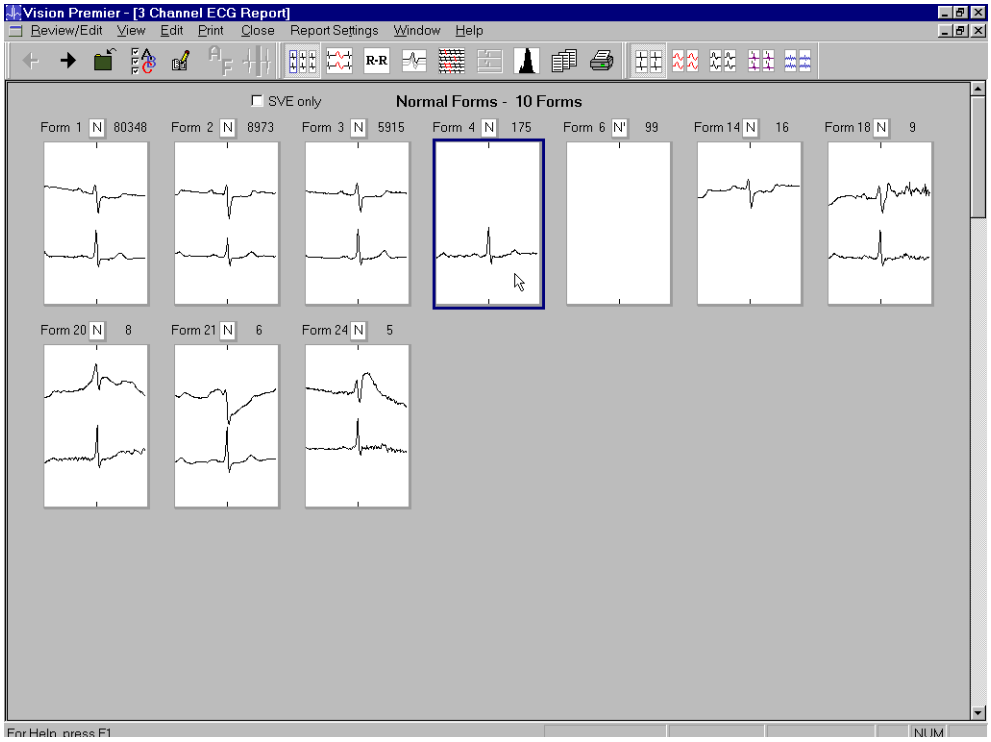
Figure 6-5
Select Forms to Merge



2. Select Merge Selected from the Edit menu. A message box appears asking you to confirm that you want to merge the highlighted forms.
3. Click [Yes] to continue. The form display reflects the merge.

   All the beats from the selected forms are now grouped into a single form. This is the form that originally had the most beats.

Figure 6-6
Merged Forms



NOTE: In the example shown above, the number of beats in Form 4 has changed to 175, which is the sum of the original form 5 and 13. After and edit or merge process the numbering of the form, which is based on number of beats in the form, may change as occurred in the above example.

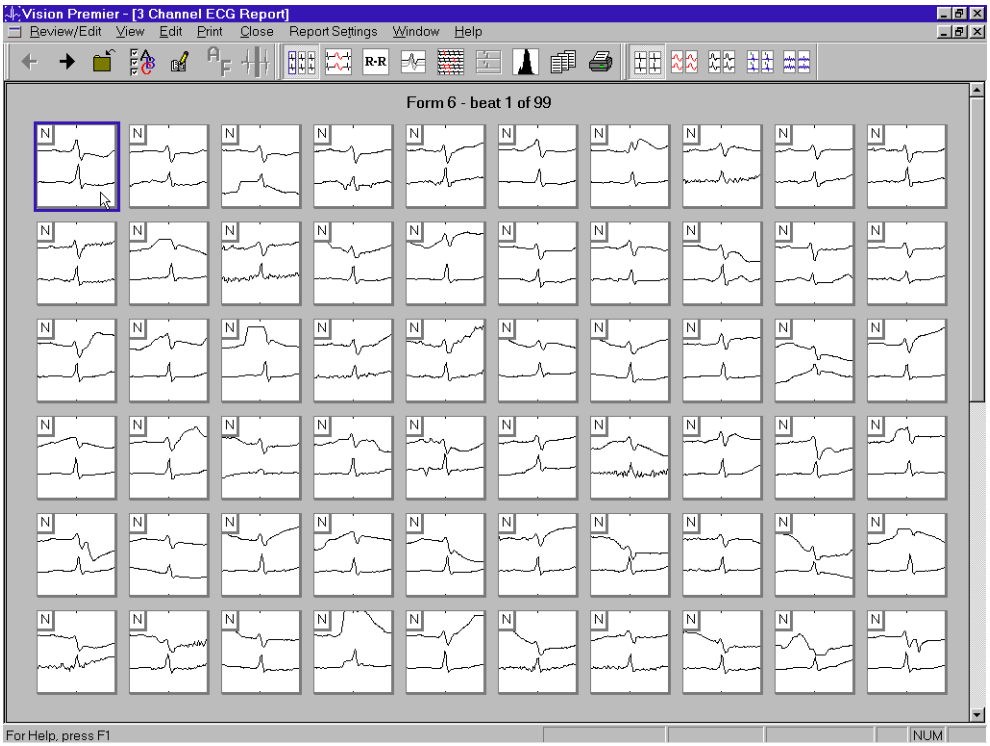
Editing Beats

When viewing forms, you may edit not only the form designation but you may also review and edit individual beats.

The Multi-Beat Display

1. Click on the desired form and select Multi Beat from the View menu. The multi-beat view of the form is displayed.

Figure 6-7
Multi-Beat Display



Every beat that is incorporated into the form is displayed in a series of screens with up to 60 beats per screen.

NOTE: Some frequently used functions can be accessed quickly by right clicking within this window. This will activate a context menu (see "Context Menus" on pg. 1-7).

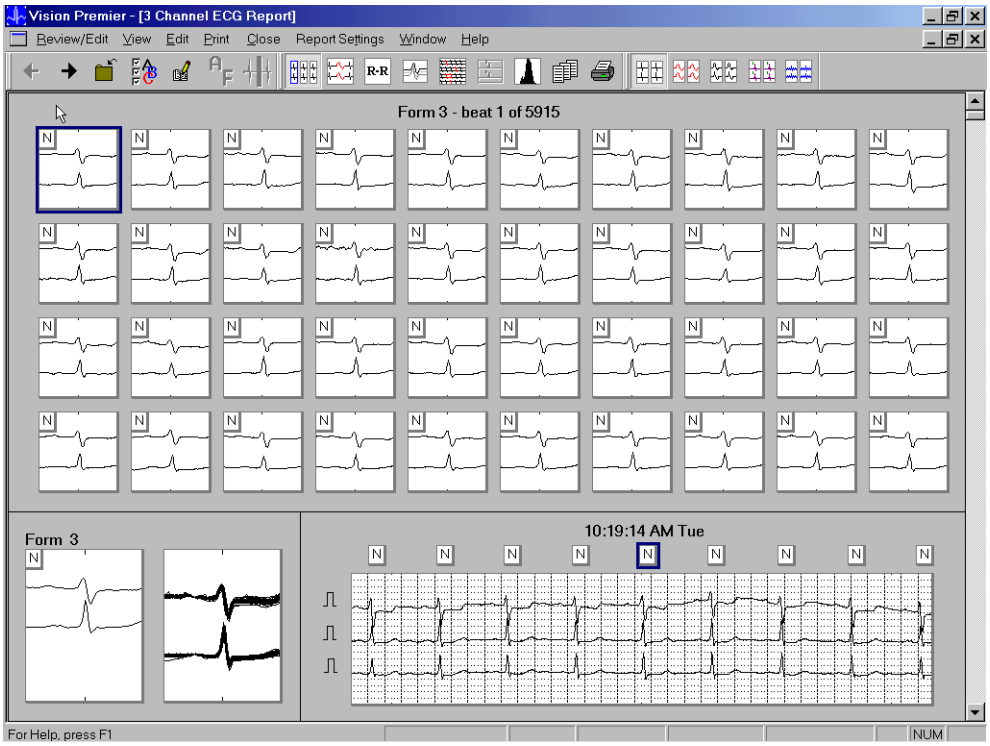
Press PG↑ and PG↓ to move through each screen or click in the scroll bar located on the right side of the window.

2. To view a beat within the context of Full Disclosure data, click on the beat to highlight it and then select Full Disclosure from the View menu.
3. To edit the beat label, right click on the beat and select the desired label from the list. The beat is automatically moved to the prime form of the correct category and the label is changed.

The Multi Beat with Superimposition Display

If, during the beat review, you need to see more detail of the selected beat, select Multi Beat with Superimposition from the View menu.

Figure 6-8
Multi-Beat with Superimposition Display



This screen displays up to 40 beats rather than 60. In the lower left of the screen is a waveform that represents the basic appearance of the beats in the form. Next to this is a composite picture of the displayed beats superimposed on one another. In the lower right corner of the screen is a diagnostic strip. There are two tic marks, one at the top and one at the bottom of this box. The beat in line with these two marks is the currently highlighted beat.

As in the Multi Beat display, you can edit the designation of an individual beat:

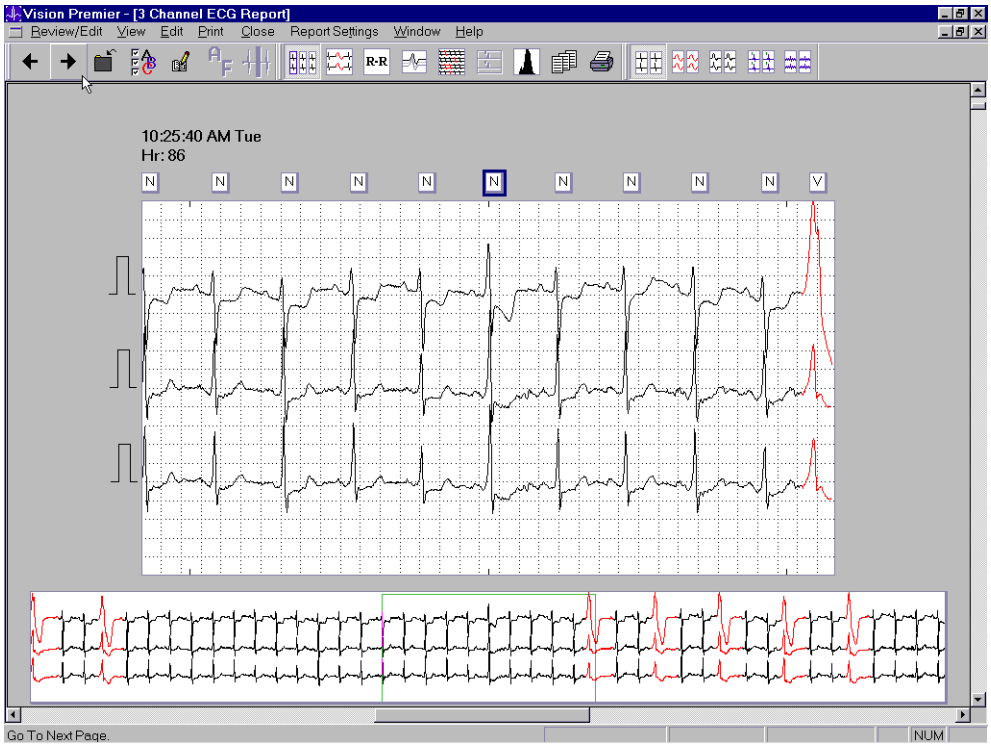
Right click on the beat and select the desired label from the list. The beat is automatically moved to the prime form of the correct category and the label is changed.

> **NOTE:** Tagged beat selections are not preserved from page to page.

The Diagnostic Strip Display

Double click on a specific beat to view the beat in more detail. The Diagnostic Strip is displayed.

Figure 6-9
Diagnostic Strip Display



This screen shows a 7-second diagnostic strip. There are six tic marks in this box, three at the top and three at the bottom. The waveform in line with the two center marks is the currently selected beat. Along the bottom of the screen is a 30-second Full Disclosure strip with the contextual viewing box centered over the same data as that displayed in the 7-second Diagnostic Strip.

To edit the beats in this screen, right click on the beat label and select the desired label from the list. The beat is automatically moved to the prime form of the correct category and the label is changed.

Chapter 7 *Reviewing & Editing Arrhythmias*

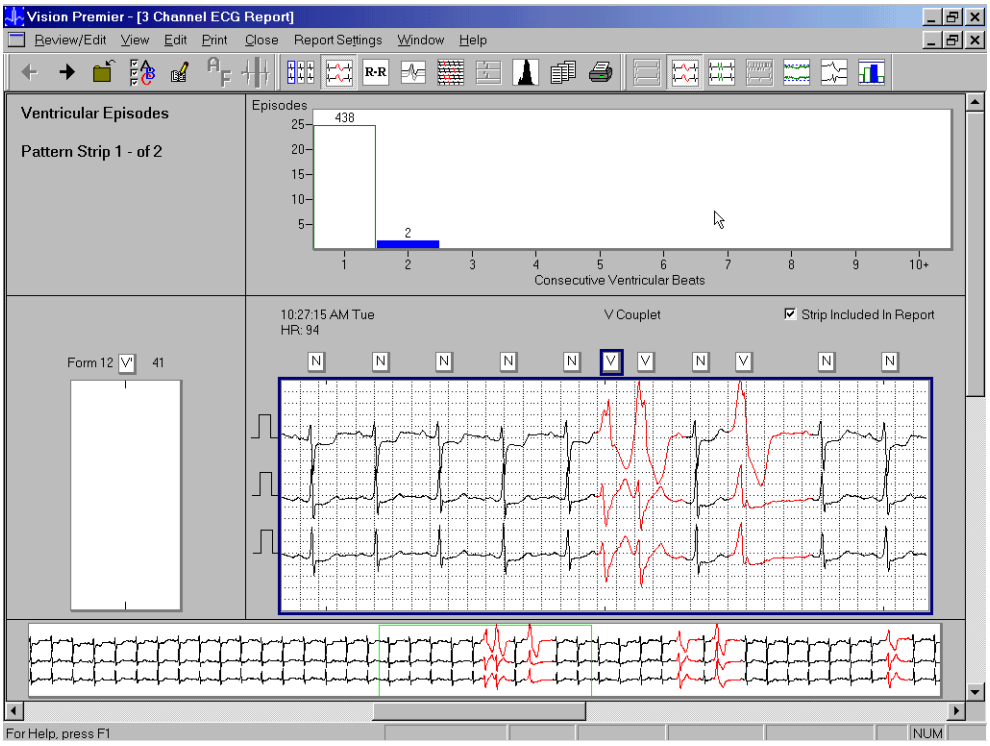
The Vision Premier™ system detects arrhythmias and annotates events indicated each time the patient presses the Event button on the recorder. These episodes are then separated into seven classifications:

- ✔ Pause Episodes
- ✔ Ventricular Episodes
- ✔ Supraventricular Episodes
- ✔ Tachycardia/Bradycardia Episodes
- ✔ Minimum/Maximum Heart Rate
- ✔ ST Episodes
- ✔ Diary Patient Episodes

Reviewing Arrhythmias

1. Start from the ***Report Manager*** window.
2. Double click the record you wish to review or edit. The ***Patient Information*** window is displayed.
3. Verify that the information displayed in the window is correct.
4. Click the Arrhythmias icon ( )in the toolbar. The ***Pattern Strip*** window is displayed.

Figure 7-1 Pattern Strip



NOTE: Some frequently used functions can be accessed quickly by right clicking within this window. This will activate a context menu (see "Context Menus" on pg. 1-7).

Most of the arrhythmia windows are very similar. These windows are all divided into three sections:

- ✔ The Histogram Distribution display
- ✔ The Diagnostic Strip and Form displays
- ✔ The Contextual View display

The Histogram Distribution Display

With the exception of the ***Min/Max Heart Rate*** window, the top right portion displays the histogram distribution for the category with the following features:

- Each column represents a subcategory for the arrhythmia. The first column represents the number of single beats containing the arrhythmia. The second column represents the number of instances with 2 consecutive beats containing the arrhythmia. This pattern continues to the far right column, which represents the number of instances with 10 consecutive beats containing the arrhythmia.
- The height of each column represents the number of episodes that are included for each subcategory. This number also appears at the top of each column.
- The columns are proportional in height. The maximum height for specific episodes is as follows:

  Isolated Ventricular and Supraventricular = 500

  Ventricular and Supraventricular Couplets = 400

  Ventricular and Supraventricular Runs = 400

  Ventricular Bigeminy = 200

  Pauses = 400

  Tachycardia and Bradycardia = 200
- The column that includes the most severe episodes is automatically highlighted when this window is opened.
- The top, left portion of this window displays the total number of episodes for the current subcategory of arrhythmia and which of these episodes is currently displayed.

For the ***Min/Max Heart Rate*** window, the top portion of the window has the following features:

- A 24 or 48-hour graph of the heart rate displayed in beats per minute (BPM)
- A blue, rectangular box that encloses 20 minutes of data on the 24 or 48-hour graph.

- The 20 minutes of data defined by the blue box is displayed at a larger scale on the right side of the screen.

The Diagnostic Strip and Form Display

The right side of this section contains a 7-second diagnostic strip. The onset of the current episode is centered in this box. Above the 7-second strip is information about the episode such as a description of the subcategory and the heart rate. Also displayed is more detailed information when applicable. For example, a Pause episode will have the pause duration displayed here.

The left side of this section displays the form that is currently highlighted in the 7-second diagnostic strip.

The Contextual View Display

At the bottom of the ***Pattern Strip*** window is a 30-second, full disclosure strip for viewing the selected beat in context with the surrounding beats. The onset of the current episode is centered in this box.

Editing Arrhythmias

Selecting Arrhythmias to Edit

The Vision Premier™ includes a certain number of representative arrhythmia strips in the Final Report. The number of strips included is determined by the System Settings. (See "System Setup" on pg. 12-1.) The Vision Premier™ selects what it considers to be the worst-case examples of each type of arrhythmia. You may, however, wish to edit or include additional strips that you feel are representative or delete those that you believe are not significant.

1. Click on the column of the subcategory you wish to review in order to view the Diagnostic Strip and Contextual View displays.
2. To view the next Pattern Strip for the current arrhythmia subcategory, press PG↓. Press PG↑ to go to the previous Pattern Strip at any time.
3. To view another arrhythmia category, click the icon in the toolbar that corresponds to the category you wish to review such as SVE Episodes ( ).

Editing an Episode

NOTE: Beats labeled as SVE may be reclassified as Normal if beats within the SVE run are manually edited. It takes two beats in a row to trigger the labelling of an SVE run. Relabelling one of these beats results in a different call by the Vision Premier™ software.

Editing the Beat Classification

Right click on the beat label above the desired beat in the 7-second strip display and select the appropriate classification for the beat from the context menu.

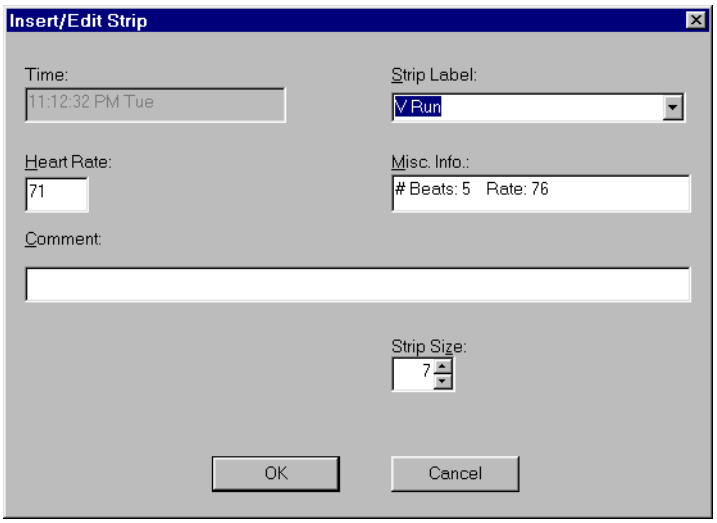
Editing the Form Classification

Right click on the form label above the form displayed at the left center of the screen and select the appropriate classification for the form from the context menu.

Including the Strip in the Final Report

1. Select the Strip Included in Report check box located above the 7-second strip display. The ***Insert/Edit Strip*** window is displayed.
2. Fill in the information as needed.

Figure 7-2
Insert/Edit Strip



3. Click [OK] to save your changes and insert the strip.

Deleting a Strip

1. When the strip you wish to delete is showing in the diagnostic strip section, press the DEL key or right click the mouse and select Delete ECG Data from the context menu. All of the beats in that strip will turn blue to indicate that they will not be used when the report is recompiled.

   NOTE: The data is not actually deleted. If you re-analyze the report, the data will be returned to it's original state.

Editing Min/Max Heart Rate

The Minimum Heart Rate and the Maximum Heart Rate events are both automatically included in the Final Report.

Click within the 24or 48-hour graph at the time period you would like to view. The Diagnostic Strip and Contextual View displays change to display the data for the corresponding time period.

To assign a different time as the Minimum Heart Rate event or the Maximum Heart Rate event:

1. Click within the 24 or 48-hour graph to place the cursor at the appropriate time period.
2. Select the Minimum Heart Rate or the Maximum Heart Rate radio button.
3. Select the Used As Minimum/Maximum HR check box.

Editing Diary Events

The Vision Premier™ system will automatically insert an episode for every time that the patient pressed the EVENT button on the recorder. You can add additional events based on what is written in the patient diary from the Pattern Strip window.

1. While in Arrhythmia Review mode, click on the Diary Patient Episodes icon ( ). The Pattern Strip window for the patient events is displayed.

Figure 7-3
***Patient Events** window*

2. In the histogram section (at the top right of the display) click the column of the episode you wish to review or edit. The column becomes highlighted. The Diagnostic Strip, Form display and 30-second Full Disclosure strip change to display the data for the selected episode.
3. Click [Review/Edit Events]. The ***Diary/Patient Event List*** window is displayed.
4. To create a new episode, enter a new time in the Diary Time edit field and click [Add].

   NOTE: DO NOT try to enter the day of the week, this will be filled in automatically based on the date and time.

5. You can delete a patient event by highlighting it in the Event List and clicking [Remove].
6. When all the desired changes have been made, click [Close] to return to the Pattern Strip window.

Chapter 8 *Viewing the ECG*

The Vision Premier™ system allows you to review and verify every beat recorded during the monitoring period. You may edit the classifications made by the system during analysis.

The Vision Premier™ system provides you with two methods of viewing the recorder ECG data:

- Full Disclosure, a page-by-page view
- Superimposition, a beat-by-beat view

Full Disclosure

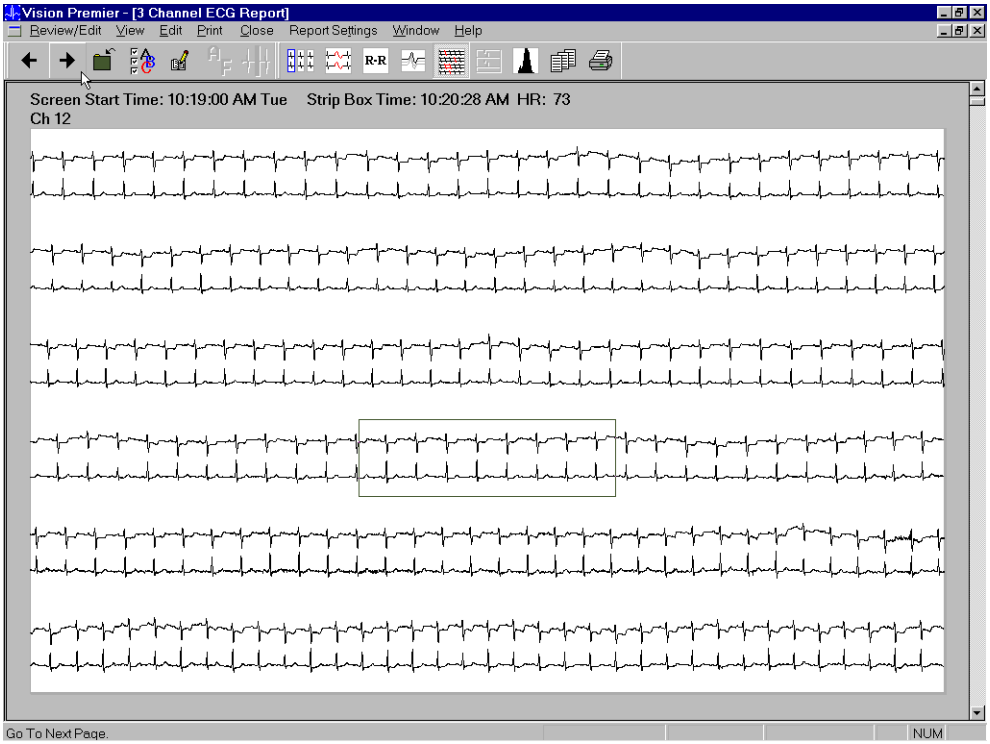
This method of reviewing the recorded ECG data is page-by-page. Each screen displays from 20 seconds of ECG data to up to 10 minutes depending on the number of channels displayed and the number of seconds displayed per line.

The display format for this window may be edited in the ***System Settings*** window (see "Display" on pg. 12-3). To change the display format for the current report only, click the Report Settings icon ( ) in the toolbar.

Displaying the Full Disclosure

1. Start from the ***Report Manager*** window.
2. Double click on the record you wish to review to open it.
3. Click the Full Disclosure Review icon ( )in the toolbar. Full-Disclosure data is displayed.

Figure 8-1
Full Disclosure



NOTE: Some frequently used functions can be accessed quickly by right clicking within this window. This will activate a context menu (see "Context Menus" on pg. 1-7).

This window shows all hours of the recording.

Abnormal beats are shown in a different color so you can quickly pick out the abnormal beats.

- ✔ Normal beats are black
- ✔ Ventricular beats are red
- ✔ SVEs are green
- ✔ Paced beats are magenta
- ✔ Artifact beats that are labelled asterisk or period are blue. Artifact beats that are labeled x, X, t, or p are the same color as the previous beat.

4. To view the data at different times, use the scroll bar to the right of the screen.

NOTE: The first five minutes of the ECG data is blue. This indicates that this data was not used to generate the report. The Vision Premier™ system locks out the first five minutes of ECG data which is used for calibration. These beats are labeled U (Uneditable) in other graphic displays.

Selecting Data to Edit or Delete

To select Full Disclosure data, you can position the cursor box over the data you wish to edit or delete, or you can use two I-beam shaped cursors to mark off specific regions.

To position the Cursor box, move your mouse cursor over the data you want to select and left click your mouse.

To use the I-beam cursors:

1. Hold down the CTRL key.
2. Click at the beginning of the section you wish to select.
3. Continue to hold the CTRL key and click again at the end of the data you wish to select.

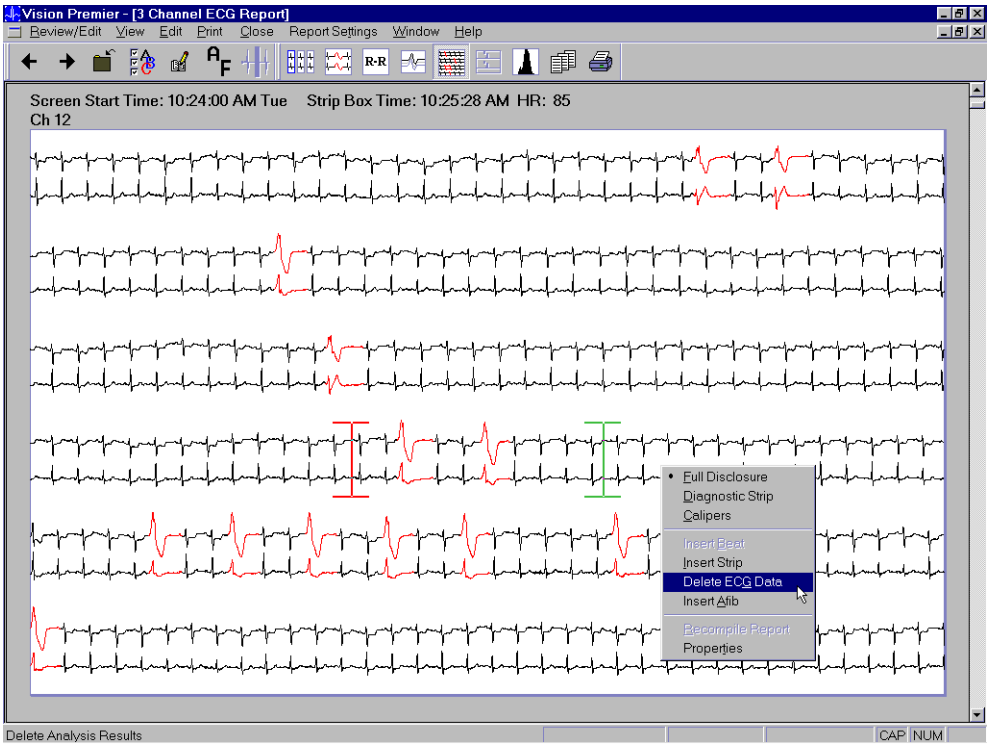
You can view and edit the selected data more closely by right-clicking within the area you have selected and choosing Diagnostic Strip from the context menu.

Most noise is removed automatically by the system during analysis, however, you may encounter recordings that contain excessive amounts of artifact that you don't want considered when analyzing a report. To handle these occurrences, the system allows you to manually delete data from analysis. Data can be deleted in amounts as small as seven seconds or as large as the entire procedure.

The deleted data is not removed from the system; it is "marked" and the system ignores the data when building a report. The deleted data appears blue to indicate that it will not be used in analysis when the report is recompiled.

To delete data, use the above procedure to select the data you wish to delete and press the DEL key on the keyboard or right click the mouse and select Delete ECG Data.

Figure 8-2
Delete ECG Data

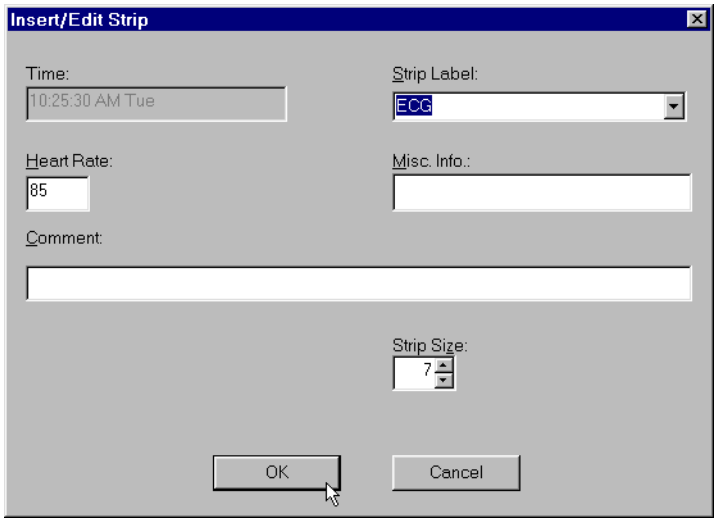


Inserting a Report Strip

Data may be manually inserted into the Final Report (see “Report Strips” on pg. 5-11).

1. Select the desired data (see “Selecting Data to Edit or Delete” on pg. 8-3).
2. Right click the mouse and select Insert Strip from the context menu. The ***Insert/Edit Strip*** window is displayed.

Figure 8-3
Insert Strip



The Time field is automatically filled in with the time of the center of the strip.

The Strip Label field is automatically set to ECG but may be changed by selecting a different label from the pull down menu.

The Heart Rate field is automatically filled in with the rate from the time of the beat closest to the center of the strip.

The Strip Size field is set in seven second increments up to 56 seconds. This field will be filled in automatically if you first select the data as described in "Selecting Data to Edit or Delete" on pg. 8-3. You will usually want to include enough data prior to the arrhythmia to aid in evaluating the arrhythmia.

The Comment field allows you to enter a brief note to indicate the reason you have inserted this strip into the final report.

3. Fill in and edit the information in this window as needed then click [OK].

Displaying a Diagnostic Strip

For a more detailed view of a beat, right-click on the selected data in the full disclosure view and select Diagnostic Strip from the context menu.

Figure 8-4
Diagnostic Strip

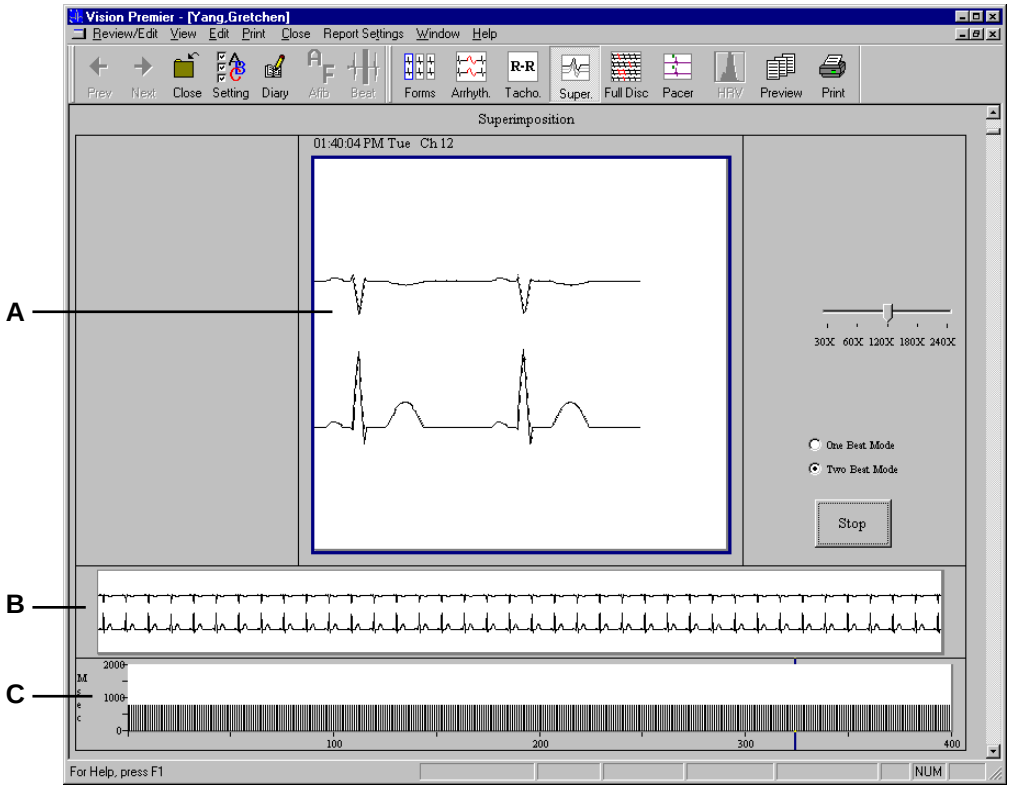
This screen shows a larger display of the contextual viewing box. The waveform in line with the highlighted label is the selected beat. Along the bottom of the screen is a 30-second Full Disclosure strip with the contextual viewing box centered over the same data as that displayed in the 7-second Diagnostic Strip.

Superimposition

In this mode, normal beats are displayed, one on top of another (superimposed). The display advances automatically. You may freeze the screen at any time by clicking [Stop].

1. Start from the ***Report Manager*** window.
2. Double click on the record you wish to review to open it.
3. Click the Superimposition Review icon ( )in the toolbar. Superimposed data is displayed.

Figure 8-5
Superimposition



KEY	
A	superimposed ECG
B	30-second full disclosure data
C	RR plot, displays up to 400 consecutive RRs (color coded to match standard beat classification; see “Full Disclosure” on pg. 8-1)

Use this screen to view superimposed beats.

- ✔ Click [Start] to begin viewing the superimposition scans.
- ✔ Click [Stop] to stop the scan.
- ✔ Click 30X, 60X, 120X, 180X, or 240X to select the speed of the scan (30X is approximately 30 times the actual speed of the recording).

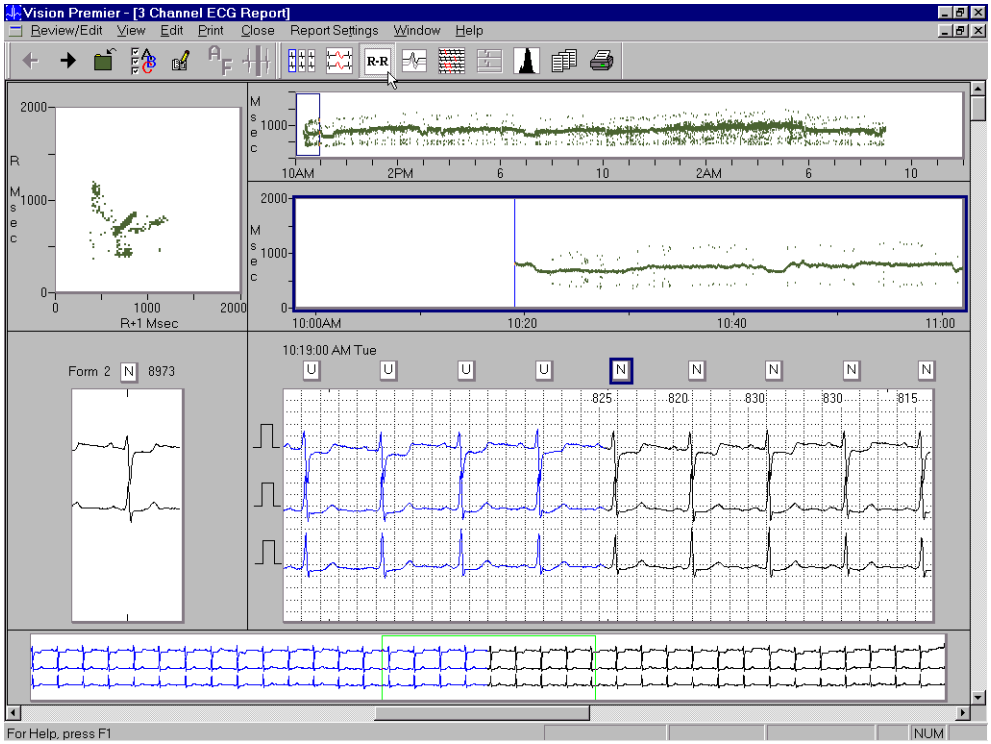
Chapter 9 *Reviewing the Tachogram*

Tachogram Review allows you to view and correct all of the RRs for the entire Holter procedure.

To review the Tachogram:

1. Start from the ***Report Manager*** window.
2. Double click the record you wish to review or edit. The ***Patient Information*** window is displayed.
3. Verify that the information displayed in the window is correct.
4. Click the Tachogram Review icon (R-R)in the toolbar. The ***Pattern Strip*** window is displayed.

Figure 9-1
Tachogram Review



NOTE: Some frequently used functions can be accessed quickly by right clicking within this window. This will activate a context menu (see "Context Menus" on pg. 1-7).

This screen is divided into three sections:

- ✔ The Histogram Distribution and Poincare Plot displays
- ✔ The Diagnostic Strip and Form displays
- ✔ The Contextual View display

The Histogram Distribution and Poincare Plot

The top section contains a procedure graph which displays all of the raw RR values. There is a box cursor within this graph which spans one hour of data.

Below the graph is a higher resolution graph showing an enlarged display of 64 minutes of raw RR values. With 2 additional minutes on either side, this box represents the 60 minutes of data covered by the cursor in the graph above it. There is a cursor in this box which represents the center of the 7-second strip displayed in the Diagnostic Strip.

The 1-hour Poincare plot to the left of this section displays the plot of the last RR value to the next RR. This data is the same data that is covered by the cursor in the graph.

You can click anywhere within the two graphs to move the cursors. Clicking within the Poincare plot has no effect on cursor movement.

For more precise cursor movement, make sure this section has focus (appears highlighted) and use the or key to move the 1-hour cursor box 1 minutes to the left or right respectively. For even more precise movement, hold down the key while using the arrow keys to move the cursor 2 seconds to the left or right.

The Diagnostic Strip and Form Display

The Diagnostic Strip and Form display is below the Histogram and Poincare Plot. To the right of this section is a 7-second strip. The onset of the current episode is centered in this box.

To the left of this section the Form is displayed for the currently highlighted beat (see "Reviewing & Editing Forms" on pg. 6-1").

You can edit tachogram data in two ways:

- ✔ Beat classification
- ✔ Form classification

Editing is done exactly as it is done while reviewing Forms.

Editing the Beat Classification

Right click on the beat label above the desired beat in the 7-second strip display and select the appropriate classification for the beat from the context menu.

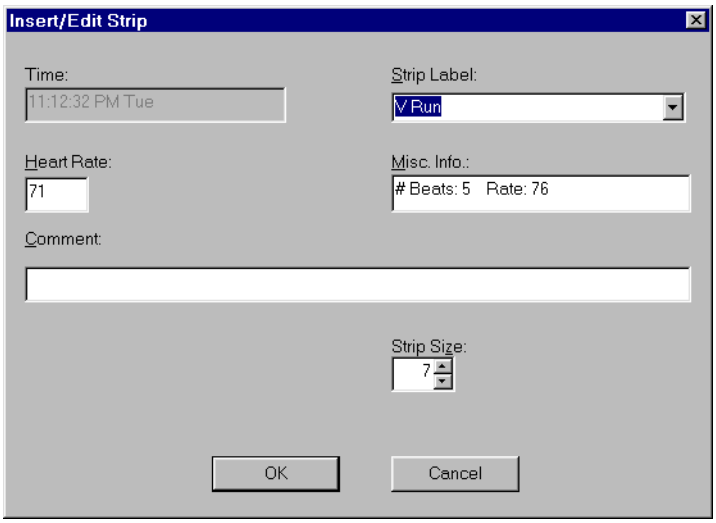
Editing the Form Classification

Right click on the form label above the form displayed at the left center of the screen and select the appropriate classification for the form from the context menu.

Including the Strip in the Final Report

1. Press the [Insert] key on the keyboard. The ***Insert/Edit Strip*** window is displayed.
2. Fill in the information as needed.

Figure 9-2
Insert/Edit Strip



3. Click [OK] to save your changes and insert the strip.

The Contextual View Display

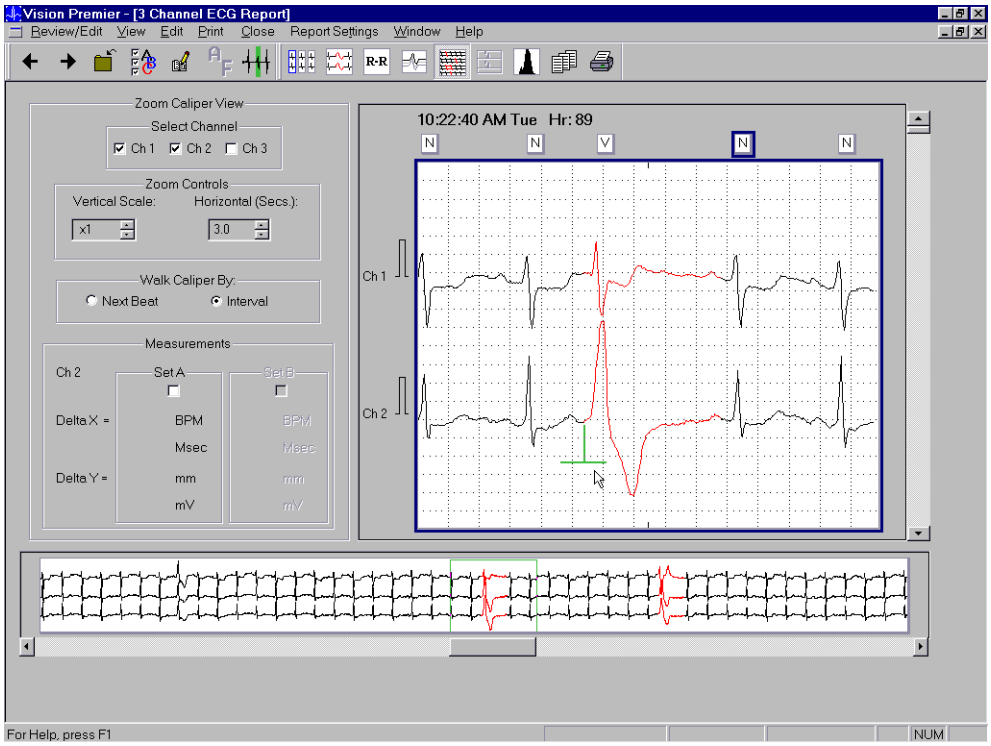
The bottom section is a 30-second, full-disclosure strip for contextual viewing. The onset of the current episode is centered in this box.

Chapter 10 *Calipers*

This function is available from any ECG display to allow the user to make precise measurements on screen.

Select Calipers from the View menu. The ***Calipers*** window is displayed.

Figure 10-1
Calipers Display



Select the checkbox for each channel that you wish to enable. Select the desired vertical scale and horizontal time base. The zoom controls allow the vertical scaling to be set to x4, x2, x1, x.5, and x.25. The vertical scaling will only effect the channel that is active. A green, inverted “T” marker notes the active channel. Horizontal time base can be set to 7.0, 4.0, 3.0, 2.0, 1.0 or 0.5 seconds. The horizontal time base setting applies to all channels that are currently displayed.

The Marker can be moved by using the keyboard or by clicking with left mouse button. The following keyboard controls are available:

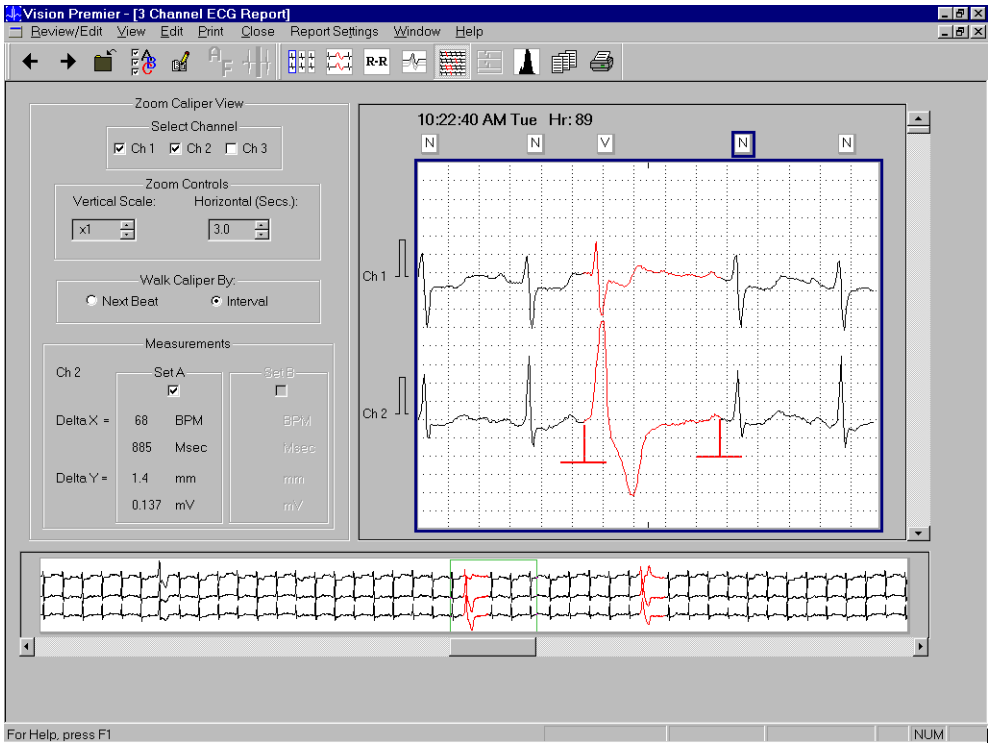
↑ and ↓ will advance the marker up or down to other channels.

← and → will move the marker left or right by 10% of screen size. CTRL combined with ← and → will advance the marker left or right at a 5-msec interval.

Press ENTER to lock the first marker. The first marker will turn red and a second green marker will appear. Move this marker to the desired location and press ENTER again to lock it into place.

To unlock or reset the calipers, press the C key or un-check the Set A check box.

Figure 10-2
Set Calipers



The data for the active channel is indicated in the left side of display under measurements. DELTA X measurements are the absolute difference between the two markers calculated in BPM and msec. DELTA Y measurements are the difference between the markers calculated in mm and mV. The sign is referenced to the first caliper locked. Measurements are displayed after the first caliper is locked.

> **NOTE:** Set B values under Measurements are not functional at this time.

After both calipers are locked, you may "walk" the calipers. Press the ← or → key to move the calipers to either the Next Beat or the preset Interval. With Next Beat, the first marker's position relative to the closest beat is used as well as the distance to the second marker.

You may edit the beat classification by right clicking on the beat label above the desired beat and selecting the appropriate classification for the beat from the context menu.

The bottom part of the display shows a contextual view of the currently selected beat.

Chapter 11 *Report Editing Enhancements*

Insert Beat

This function is available from most ECG displays and allows you to label a designated beat in a patient ECG.

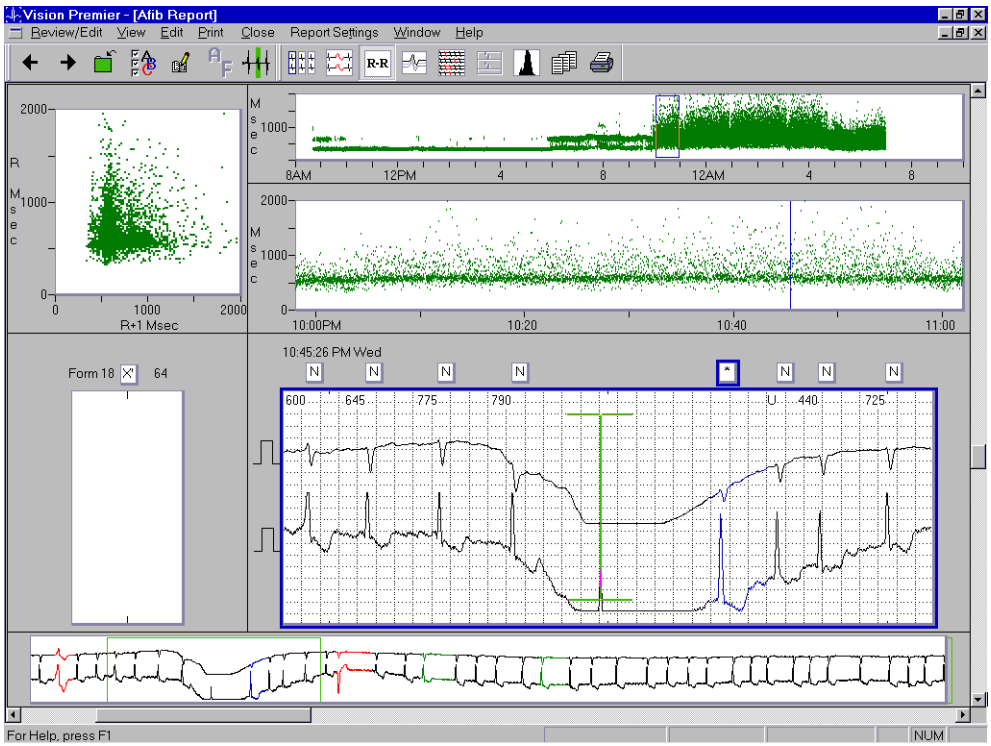
To insert a beat Marker at a designated location, left click the mouse while holding the CTRL key down. The single Marker notes where Beat Insert will take place.

The Marker can be moved by using the keyboard or by clicking on the new location. The following keyboard controls can be used to move the Marker:

- The ← and → keys will move the Marker left or right in 100 msec intervals.
- Press and hold the CTRL key while using the ← and → keys to move the Marker left or right in 5 msec intervals.

The display below is a Tachogram Review showing the Insert Beat I-beam marker.

Figure 11-1
Insert Beat



NOTE: When inside the Calipers view, two color Markers may be present inside the ECG window. To remove the inactive Marker, left click your mouse on the ECG day and time text above the ECG strip.

Once you have aligned the Marker with the beat you wish to label, click on the Insert Beat icon ( ) in the tool bar or click the right mouse button and select Insert Beat from context menu. Select the beat classification for the beat you designated.

Insert Atrial Fib/Flutter

This function is available from most ECG displays and allows you to label a designated period of Afib/Flutter in a patient ECG.

To insert a Marker, left click the mouse while holding the CTRL key down. The single Marker notes the start of the designated Afib/flutter episode.

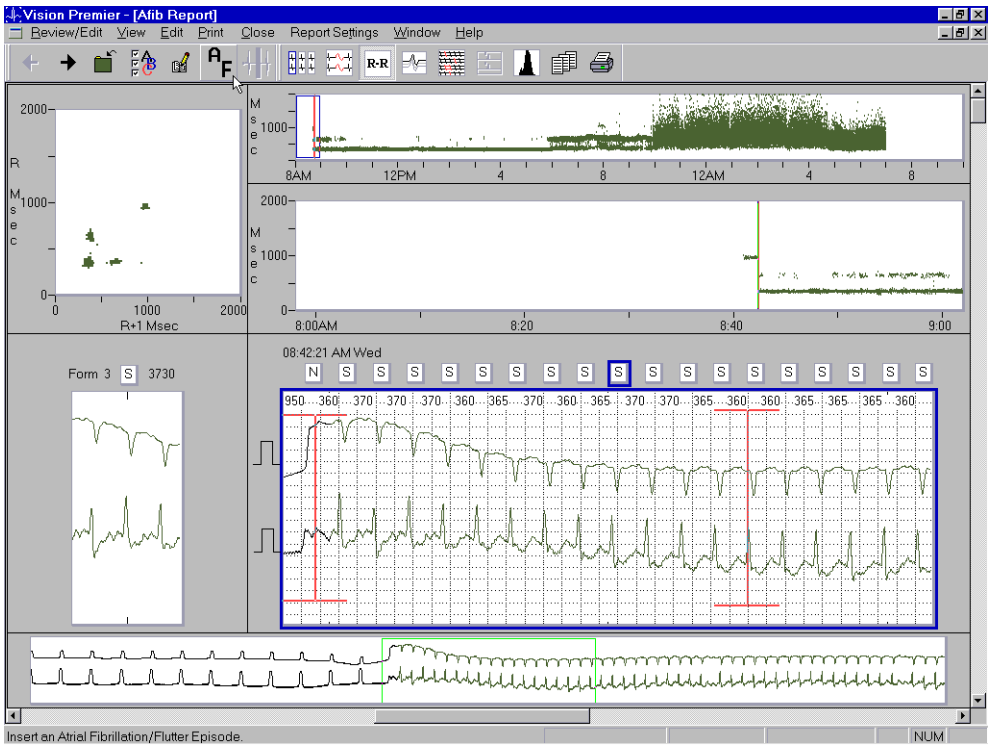
The Marker can be moved by using the keyboard or by clicking on the new location. The following keyboard controls can be used to move the Marker:

- The ← and → keys will move the Marker left or right in 100 msec intervals.
- Press and hold the CTRL key while using the ← and → keys to move the Marker left or right in 5 msec intervals.

To insert a second Marker, left click the mouse while holding the CTRL key down. This second Marker notes the end of the designated Afib/flutter episode. (The second Marker can be moved in the same way as the first.)

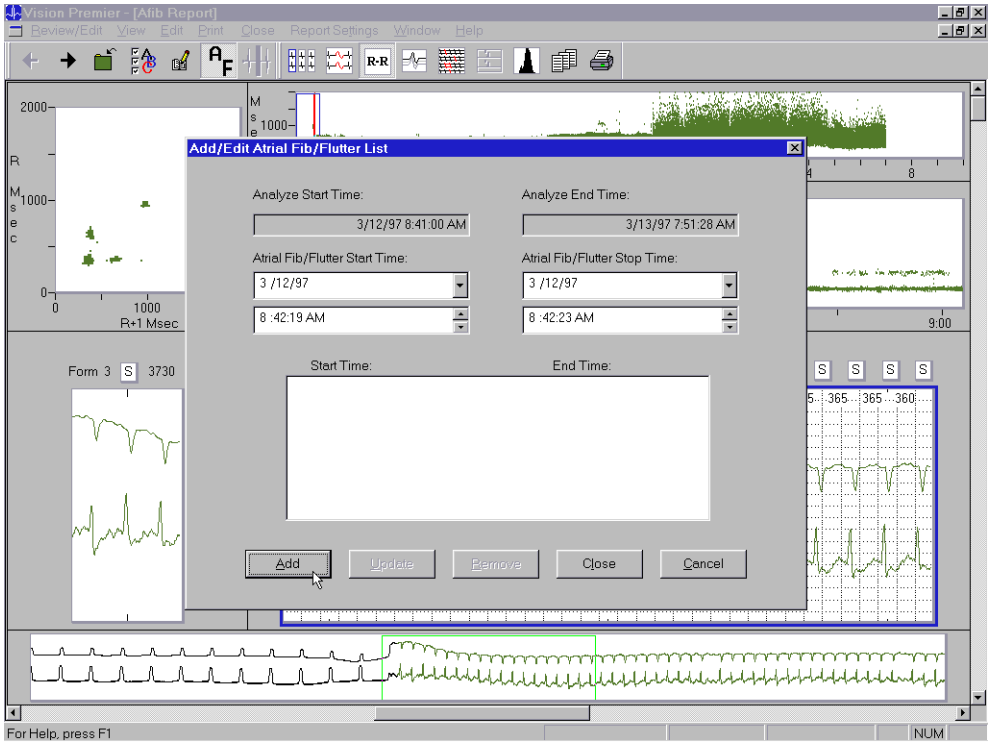
The display below shows the two Afib/flutter I-beam markers designating the episode.

Figure 11-2
Insert Afib/Flutter



Once you have aligned the Markers with the segment you wish to label, click on the Insert Afib icon (A_F) in the tool bar or click the right mouse button and select Insert Afib from the context menu to open the *Add/Edit Atrial Fib/Flutter List* window.

Figure 11-3
Add/Edit Atrial Fib/Flutter List



The Analyze Start Time designates the position of the first Marker. The Analyze Stop Time designates the position of the second Marker. The duration of the Atrial Fib/Flutter episode is the time between the two Markers. You can edit the start and stop times to modify the duration.

To Add an Atrial Fib/Flutter episode to the list, click the [Add] button; overlapping episodes will be merged.

To Update an existing Atrial Fib/Flutter episode, click the [Update] button; overlapping episodes will be merged.

To Remove an existing Atrial Fib/Flutter episode, click the [Remove] button.

When all the desired modifications to the list have been made, click the [Close] button to save your modifications or click the [Cancel] button to abort your modifications.

Chapter 12 *System Setup*

Before using your Vision Premier™ system, you may wish to spend a few minutes to configure the system to suit your individual needs. Use the Windows® Control Panel to set the formats for time and date. All other setup is performed from within the Vision Premier™ application, as described in this chapter.

The Vision Premier™ System Settings option allows you to set various parameters of the system setup and report configurations.

To access the System Settings:

1. Start from the ***Report Manager*** window.
2. Click on the System Settings icon ( ) in the toolbar. The ***System Settings*** window is displayed.

   There are 8 pages in this window:

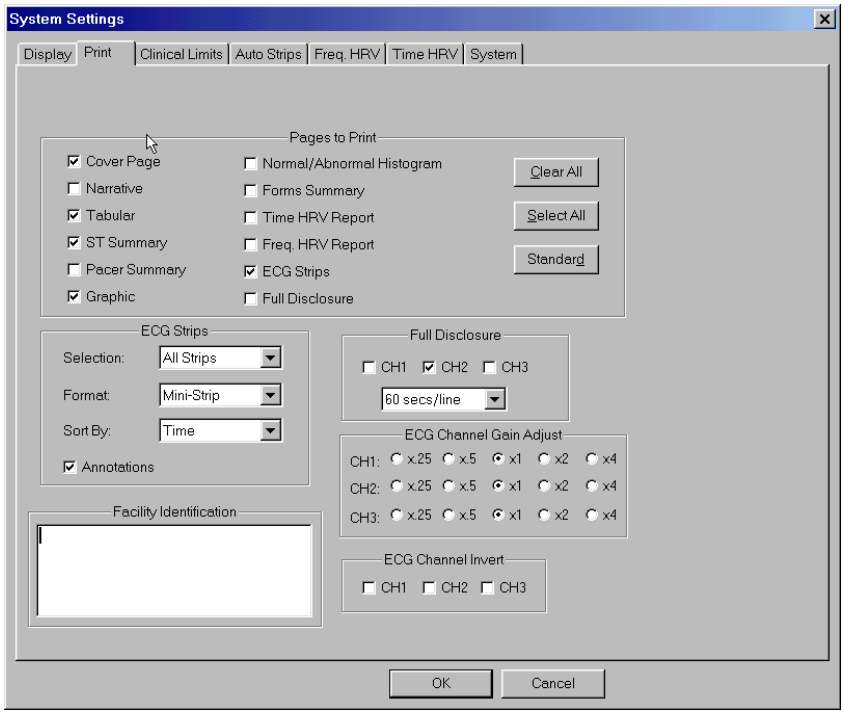
   - ✔ Display
   - ✔ Print
   - ✔ Clinical Limits
   - ✔ Auto Strips
   - ✔ User Strips
   - ✔ Freq. HRV
   - ✔ Time HRV
   - ✔ System

   To switch to a different page, click on the appropriate tab. The Print page is displayed when this window is first opened.

   NOTE: The two tabs, Frequency HRV and Time HRV, are described in your HRV option operating instructions if you have purchased the HRV option.

Print

Figure 12-1 System Settings – Print Settings

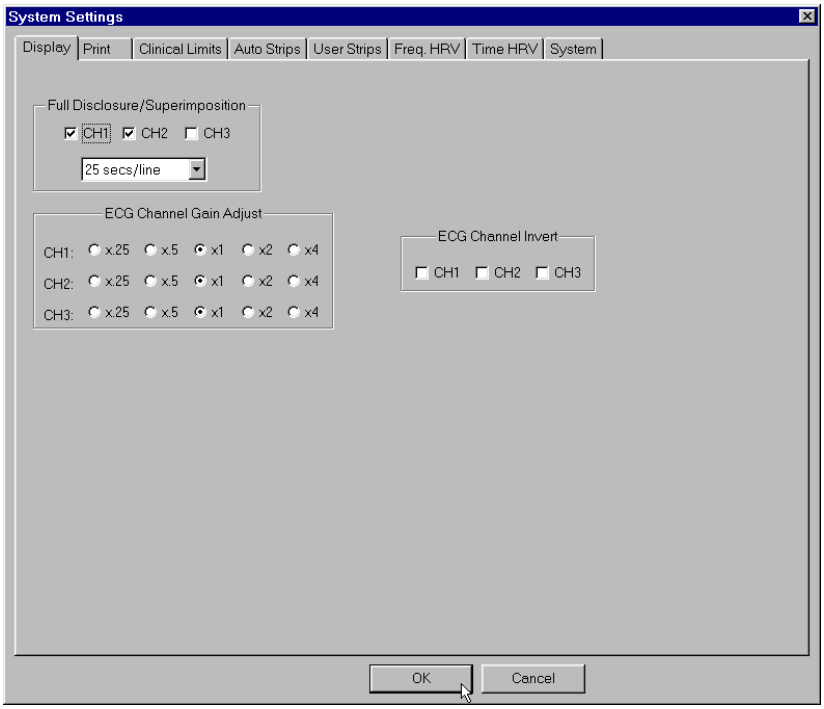


Print Settings	
Physician	This is the name of the person who will be using the customized settings. This list is editable in the Acquire Wizard (see “Acquiring & Analyzing Patient Data” on pg. 3-1). When acquiring a new record, you are given the option of selecting the name of the Overreading Physician. The name you select there will determine which customized System Settings are used to analyze and print that patient’s report.
Pages to Print	Select which report pages will print when Print Report is selected.
ECG Strips	**Selection** All Strips or User Inserted. **Format** Mini-Strip or Diagnostic. Mini-Strip is a paper-conserving, small print format and Diagnostic is a larger, diagnostic-quality print format. **Sort By** Time or Category. When sorted by Time, the strips are printed in chronological order. When sorted by Category, like strips are printed together.
Annotations	Include beat annotations above each strip in the printout.

Print Settings	
Full Disclosure	Select which channels to print and what resolution to use when printing the full disclosure (10, 30 or 60 seconds per line).
ECG Channel Gain Adjust	Adjust the amplitude for one or more channels only if the patient's signal is consistently weak or strong.
ECG Channel Invert	Invert the signal from one or more channels.
Facility Identification	Type the name and address information as desired for your facility. This information will appear on the cover page of report printouts. The first line that you type in this field will appear at the top of every printed page of the report.

Display

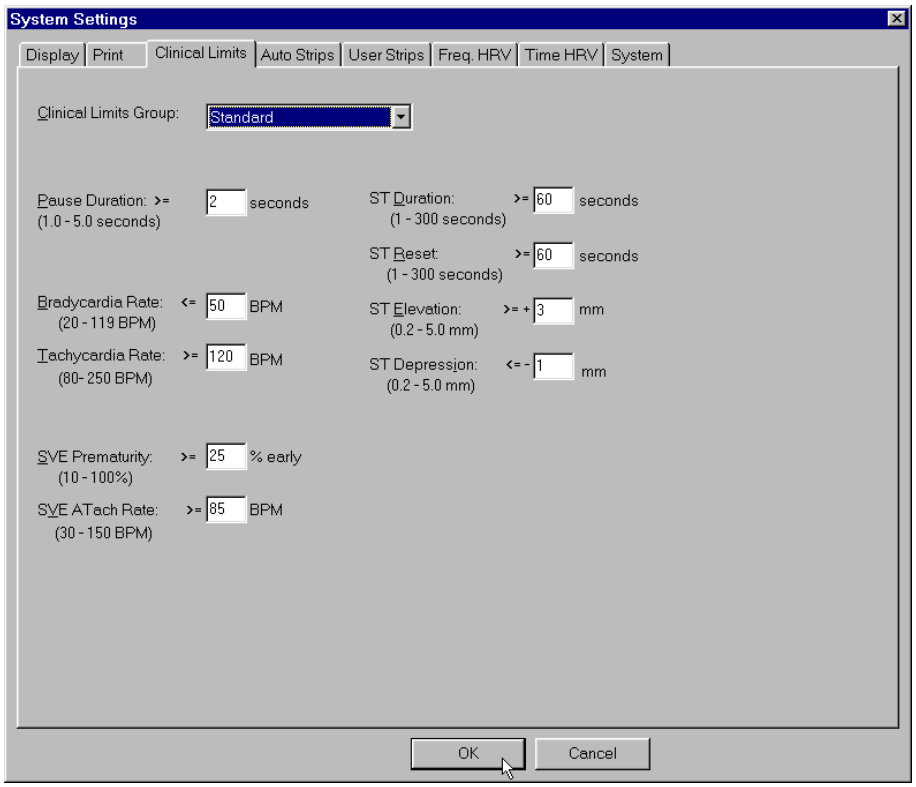
Figure 12-2
System Settings – Display Settings



Display Settings	
Full Disclosure/ Superimposition	Select which channels are displayed and the number of seconds of data are displayed on each line (10, 15, 25, or 30 seconds per line). NOTE: No data is excluded from analysis. NOTE: The display will be larger if there are fewer seconds displayed per line.
ECG Channel Gain Adjust	If the patient's data is consistently weak or strong in one or more channels, adjust the displayed amplitude for those channels.
ECG Channel Invert	Invert the display for one or more channels. NOTE: There is no visual indication on the screen or printouts that this inversion has been made.

Clinical Limits

Figure 12-3
System Settings –
Clinical Limits Settings

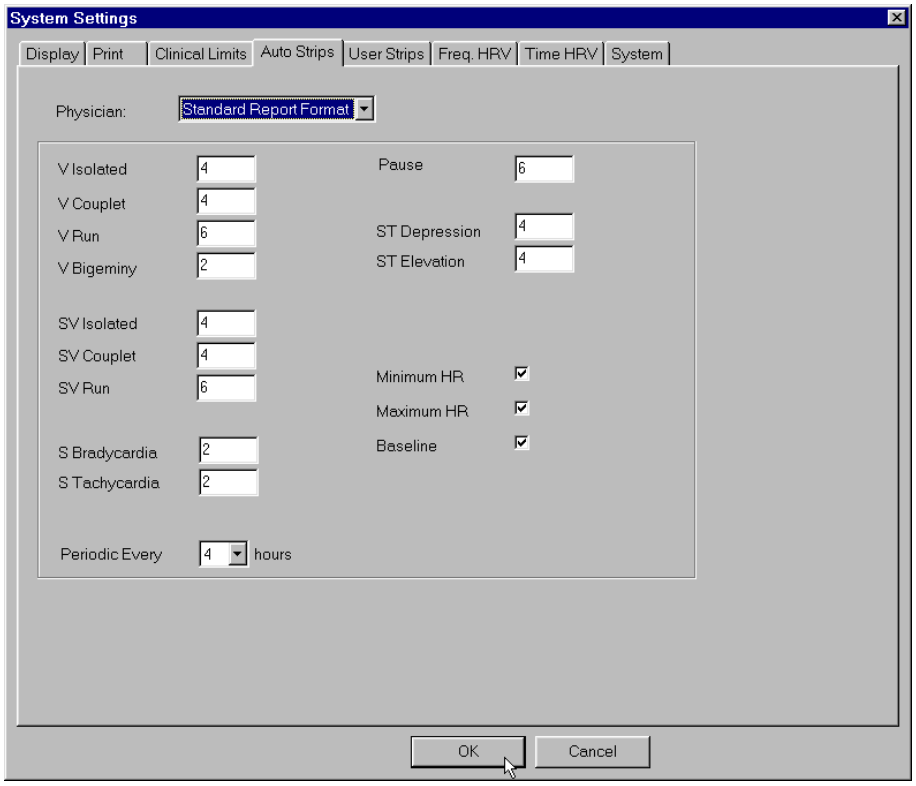


Clinical Limit Settings	
Clinical Limits Group	Standard, Paced, Pediatrics, Custom 1, or Custom 2. Select which set of clinical limits should be applied to the patient data. You can configure all 5 categories to suit your needs.
Pause Duration	The amount of time (in seconds) that must elapse with no ECG detected before a pause is declared.
Bradycardia Rate	The rate the heart rate must fall below before a bradycardia event is declared.
Tachycardia Rate	The rate the heart rate must exceed before a tachycardia event is declared.
SVE Prematurity	The percentage that a normal morphology beat must be premature before an SVE event is declared.
SVE ATach Rate	The rate a beat RR must exceed before an SVT is declared. Supports more accurate detection for bradycardiac patients or patients with an underlying low heart rate.
ST Duration	The time (in seconds) an ST episode must exceed the threshold limits before being declared an event.

Clinical Limit Settings	
ST Reset	The time (in seconds) an ST episode must not exceed the threshold limits to end the declared event.
ST Elevation	The amplitude threshold (in millimeters) the ST segment must exceed above the baseline before being declared.
ST Depression	The amplitude threshold (in millimeters) the ST segment must exceed below the baseline before being declared.

Auto Strips

Figure 12-4
System Settings –
Auto Strip Settings



Use this screen to tell the system how many strips of each category you want included in the Final Report. Any combination of these strips may be selected for a maximum of 255 total strips.

Select a Physician from the list. This is the name of the person who will be using the customized System Settings. The Physician list is editable in the Acquisition Wizard (see "Acquiring & Analyzing Patient Data" on pg. 3-1).

When acquiring a new record, you are given the option of selecting the name of the Overreading Physician. The name you select there will determine which customized System Settings are used to analyze and print that patient's report.

User Strips

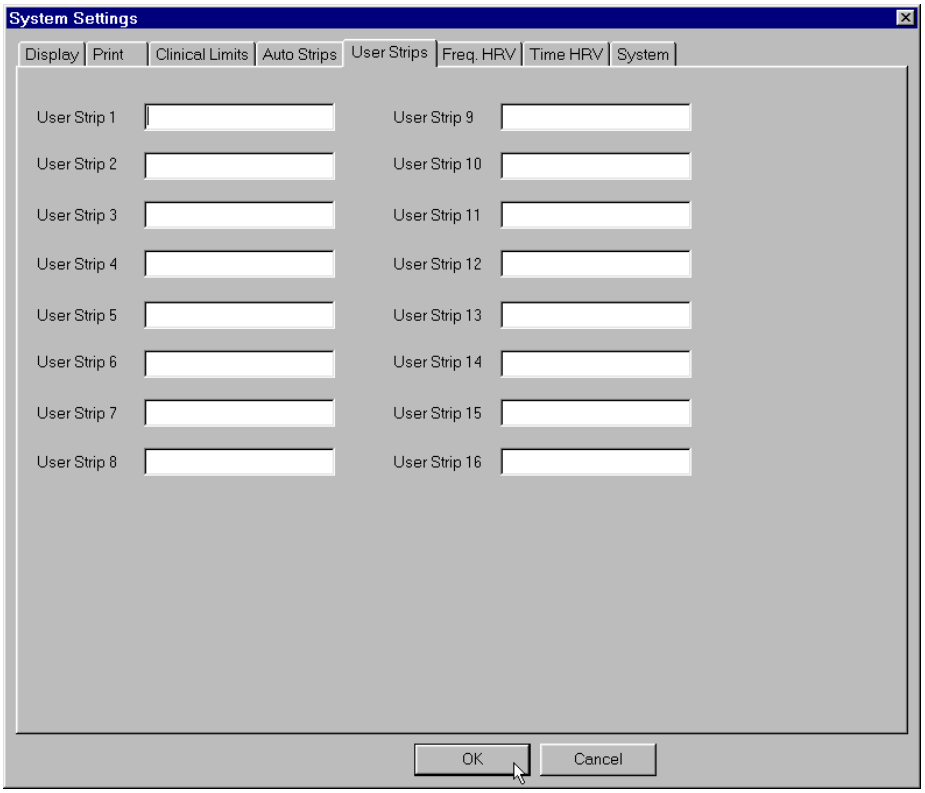
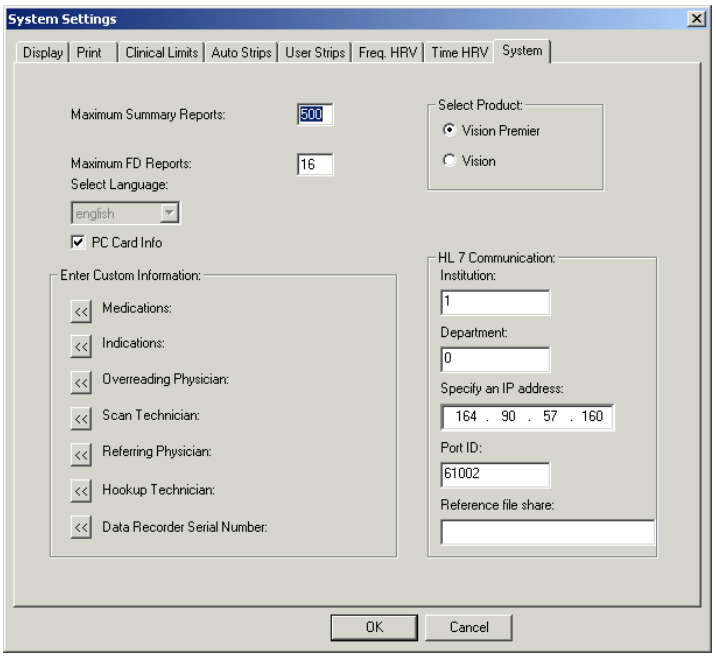


Figure 12-5 System Settings – User Strips

Use this screen to create up to 16 labels for ECG strips that may be incorporated into the Final Report.

System

Figure 12-6
System Settings – System



Maximum Reports

Use the Maximum Summary Reports and Maximum FD Reports fields to set a limit on the number of reports that can be saved in Vision Premier™. Once the limit is reached, old reports must be deleted before a new report can be acquired.

When setting these values, make sure that you have enough free space on your computer's hard drive to hold the indicated number of reports. As a general rule, one FD (full disclosure) report requires between 20 and 30 Mb of space, depending on whether the recording was 2 channel or 3 channel. One 48-hour FD report will use up to twice these amounts. Summary Reports usually require between 200K and 500 K bytes or more of space, depending on the total number of report strips and the size of each strip.

PC Card Info

Use this checkbox to enable or disable patient information entry during PC Card initialization.When the feature is enabled, the user has the option to enter patient demographic as a part of initialization. Any patient information entered during initialization is automatically saved to the record.

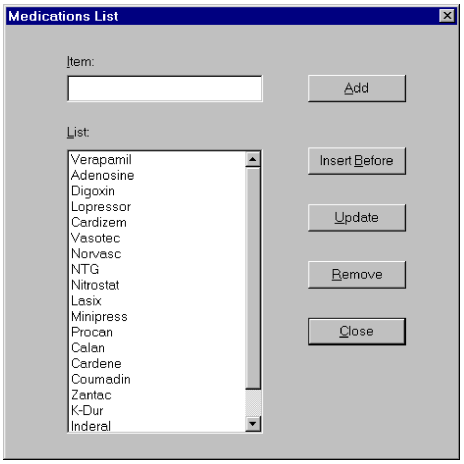
Disable this feature if you do not want the ***Enter Patient Information*** window to appear during initialization.

Enter Custom Information

Use this area to add, delete or modify the lists for medications, indications, overreading physician, scan technician, referring physician, hookup technician, and data recorder serial number.

Click on the arrows << next to the selection to view the list for the selection. For example, to view the list of medications, click on the arrows next to Medications. The ***Medications List*** window is displayed.

Figure 12-7
The Medications List



To add a new item to the list, type in the desired information and select [Add].

If you want the item to appear in a specific location in the list, highlight the item that will appear just after the new item, type the desired information for the new item, and select [Insert Before].

To delete an item from the list, highlight the item and select [Remove].

To change an existing item, highlight the item, type in the changes and select [Update].

> **NOTE:** All changes are saved automatically.

To exit the window, select [Close].

HL7 Communication

HL7 parameters must be configured in order for Vision Premier™ to communicate with the PYRAMIS® ECG Management System (see "Sending HL7 Reports" on pg. 13-4).

- ✔ Enter the IP address of the PYRAMIS machine which will be receiving the exported data.
- ✔ Enter the network location (Reference file share) for holding summary reports that have been sent as part of HL7 communication.

All other values are automatically entered with default values.

> **NOTE:** The Institution and Department numbers are derived from similar values on PYRAMIS. The Port ID number is the number for communication between Vision and PYRAMIS.

Chapter 13 *Printing and Sending Files*

Printing the Report

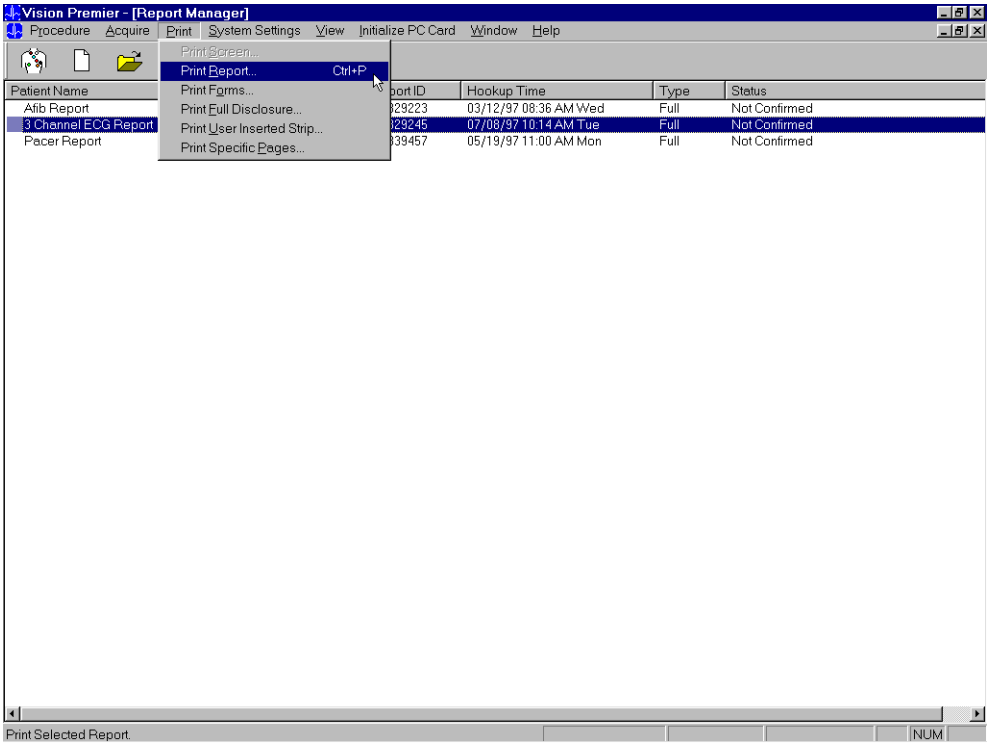
From the ***Report Manager*** window there are 5 options for printing patient data:

- ✔ Print Report
- ✔ Print Forms
- ✔ Print Full Disclosure
- ✔ Print User-Inserted Strip
- ✔ Print Specific Pages

To print patient data:

1. Highlight the desired record in the ***Report Manager*** window.
2. Click on Print in the Menu bar.
3. From the pull down menu, select the desired print option.

Figure 13-1
Print Options



Print Report

Select this option to print the entire Final Report as defined in the ***System Settings*** window (see "Print" on pg. 12-2).

Print Forms

Select this option to print all the forms as they are displayed for form review (see "Reviewing Forms" on pg. 6-2).

Print Full Disclosure

Select this option to print the entire 24 hours of patient data. The format for this printout is determined in the ***System Settings*** window (see "Print" on pg. 12-2).

Print User-Inserted Strip

Select this option to print all the strips that have been inserted manually. The format for this printout is determined in the ***System Settings*** window (see "Print" on pg. 12-2).

Print Specific Pages

Select this option to print only the Final Report pages that you select. A window similar to the ***System Settings*** window (see "Print" on pg. 12-2 for a description of this window) is displayed where you can make selections that affect only the current printout.

> **NOTE:** If the highlighted record is a summary report, then several of the options under Pages to Print will be grayed out.

Taking Pictures of the Display

With the Vision Premier™ system you can obtain pictures of the image shown on the display. This option has many uses. For example, if you are experiencing difficulties with your system, having a picture of the display is useful when consulting with Technical Support personnel.

There are several options available with the Print Screen feature:

- Obtain a picture of the entire screen display.
- Obtain a picture of the active window only.
- Obtain a printout from the printer.
- Obtain a picture that can be pasted into a document such as a WordPad document or a graphic program document.

Follow the instructions below to take pictures of the display for printing or pasting into a document.

To take a picture of the display:

- ✔ Press the <Print Scrn> key to take a picture of the entire screen.

or

- ✔ Click within the window that you want to capture. The window becomes active.
- ✔ Hold down the ALT key and simultaneously press the <Print Scrn> key.

Windows 95/98:

The ***Print*** window is displayed.

- ✔ To print the picture, select the desired printer.
- ✔ Click [OK].

or

- ✔ To paste the picture into a document, click [Cancel].
- ✔ Open the document.
- ✔ Paste the picture into the document.

Windows 2000 Professional/XP Professional:

- ✔ Open Wordpad
- ✔ Paste the picture into the document.

Faxing Reports

NOTE: To use the Fax option, you must have a modem and fax software installed. For additional information, see the Vision Series Setup Guide.

1. Print as you would to a normal printer (see "Printing the Report" on pg. 13-1 and "Taking Pictures of the Display" on pg. 13-2).
2. When the ***Print*** window is displayed, select Microsoft Fax as the name of the printer.
3. Click [OK].

Sending Reports

Sending HL7 Reports

NOTE: This feature is optional on Vision Premier™.

If the HL7 communication option has been installed on Vision Premier™, users can send data to compatible management systems, such as PYRAMIS® ECG management system. When an HL7 report is sent, the following information is included: cover page, VE tabular, SVE tabular, pacer tabular, narrative, and ST summary.

To send a report in HL7 format:

1. Highlight the desired record in the ***Report Manager*** window.

   NOTE: To select more than one report, hold down the Control key.

2. Select Procedure from the menu bar.
3. From the pull down menu, select Send and then HL 7 Report.

The report is sent to the IP address and port ID listed in the ***System Settings*** window (see "HL7 Communication" on pg. 12-8).

Sending Summary Reports Using E-Mail

Users can e-mail summary reports to recipients using the host site's e-mail application (for more information on summary reports, see "Summarizing Reports" on pg. 4-6). Summary reports are included as an attachment on e-mails, and can be viewed on systems installed with the Vision™ Series Holter Report Viewer (for more information, see the Vision™ Series Holter Report Viewer Installation Instructions and Operating Instructions).

To e-mail a summary report:

NOTE: Vision Premier™ automatically generates a summary report if one does not already exist for a record. The summary report is then deleted once the e-mail is sent.

1. Double click the record to open it.
2. Select Report Settings from the menu bar to view the print settings for the report.
3. Make changes as necessary. Click [OK].

   NOTE: In order for the e-mail recipient to print each page in the summary report, each active checkbox in **Pages to Print** must be selected.

4. Close the report.

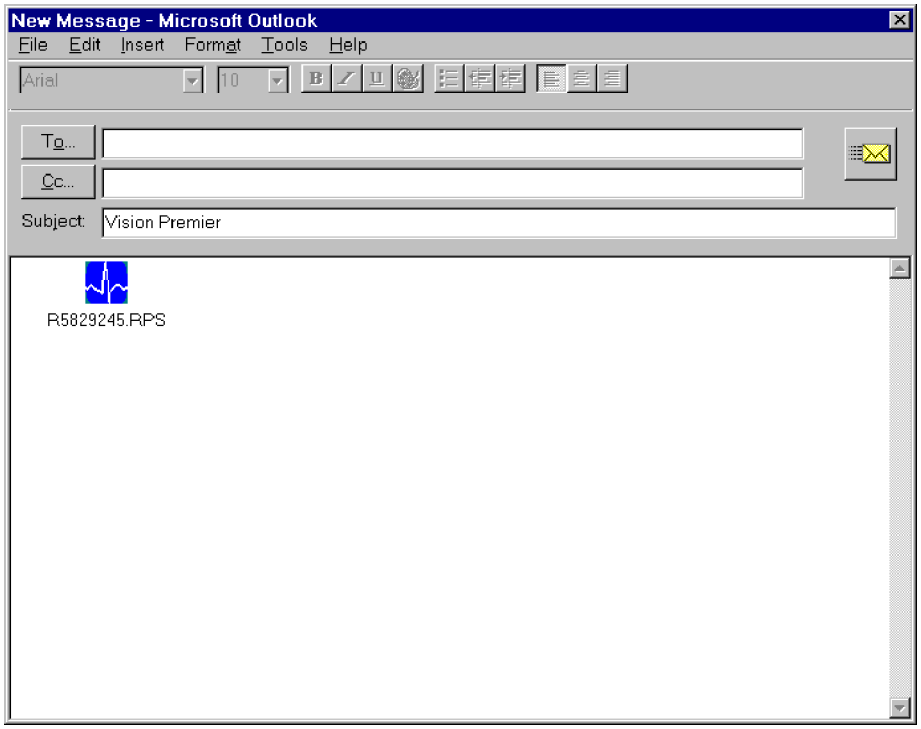
5. With the report highlighted in the ***Report Manager*** window, select Procedure from the menu bar.

   NOTE: To select more than one report, hold down the Control key.

6. From the pull down menu, select Send and then Mail Recipient.
7. The e-mail form is displayed.

   NOTE: The information provided here includes details that are specific to Outlook® Express*. This is for illustration purposes only; various e-mail applications can be used.

Figure 13-2
E-Mail form in Outlook Express



8. Enter e-mail addresses as desired.
9. Press the send key  to e-mail the report.

   CAUTION: Edits made directly to Holter report e-mail attachments cannot be saved. To edit Holter reports received via e-mail, first save the attached report to a secure file location (requires an .rps file extension).

*Outlook® Express is a registered trademark of Microsoft corporation

Exporting Reports

Holter report data can be converted into text format for additional analysis and reporting. Conversion occurs through the process of exporting data. Exported data can be imported into spreadsheets.

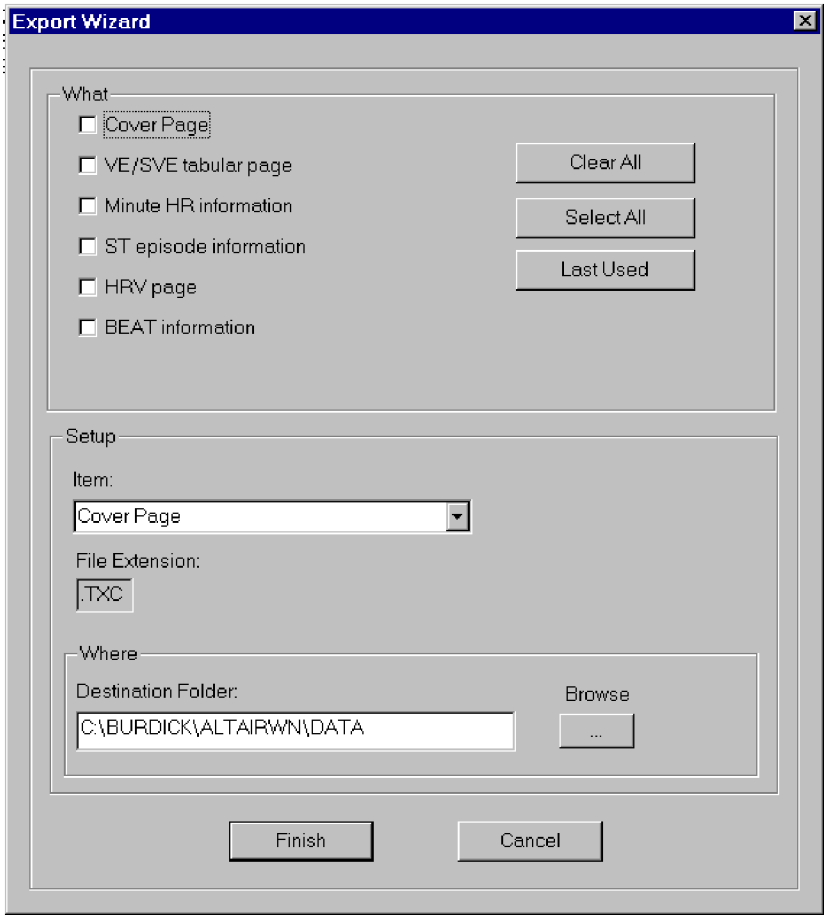
To convert Holter report data to text:

1. Highlight the desired record in the ***Report Manager*** window.

   NOTE: To select more than one message, hold down the Control key.

2. Select Procedure from the menu bar.
3. From the pull down menu, select Export.
4. The ***Export Wizard*** window will appear to guide you through the steps necessary to setup the export function.

Figure 13-3
The Export Wizard



5. Select which information you would like to export under What.
6. To change the destination folder, select an item from under Setup. Click the [Browse] button to locate and select the new drive or folder you wish to use.

NOTE: You must change the destination for each item individually.

7. Once all information has been configured as desired, click on the [Finish] button.

Accessing Exported Data

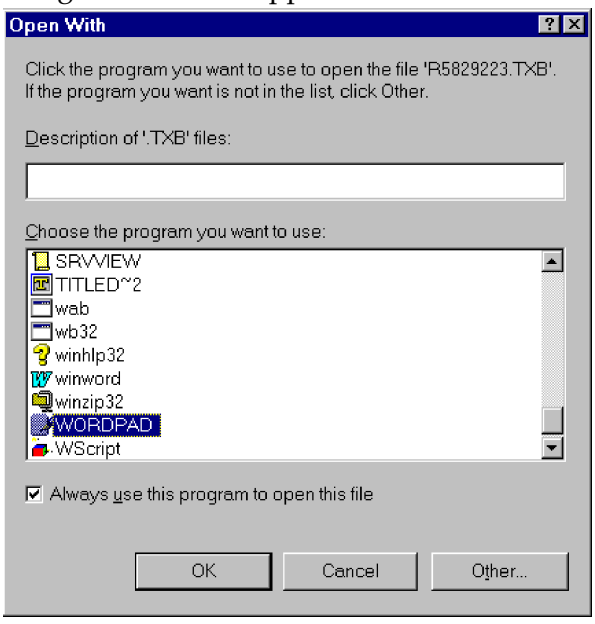
One file is created for each item that is selected under What in the ***Export Wizard*** window (items include, for example, cover page, VE/SVE tabular page, etc.). Each exported item has a different file extension—for example, the file extension for a Cover Page is .txc. All files, however, can be opened as text.

To open exported files:

1. Open the location where the exported data was saved (the location given for Destination Folder in the ***Export Wizard*** window).
2. Click on the file you wish to open. Use the table below to identify each file.

File Extension	Item	Data Format
.txc	Cover Page	tab delimited
.txt	VE/SVE tabular page	tab delimited
.txm	Minute HR information	comma delimited
.txs	ST episode information	comma delimited
.txh	HRV page	tab delimited
.txb	BEAT information	comma delimited

3. The following window will appear.



Select a program to open the file. The data can be opened using word processing programs (such as Microsoft Word), text viewing programs (such as Notepad or Wordpad), and spreadsheets (such as Microsoft Excel).

Chapter 14 *Maintenance & Troubleshooting*

No calibration is needed for your Vision Premier™ system. For maintenance and cleaning procedures, consult the documentation that came with your computer.

Contact an authorized service agent immediately if:

- ✔ The equipment is dropped or subjected to some other mechanical stress.
- ✔ Liquid is spilled on the equipment.
- ✔ The equipment is not functioning as described in this manual.
- ✔ Parts of the enclosure are cracked or missing.
- ✔ Any connector shows signs of deterioration such as cracking.

All functions of the Vision Premier™ system are designed to be user-friendly and easy to understand. If a questions arise or you would like additional information, contact your local representative or Burdick Technical Support Department at (800) 333-7770 or (608)764-1919.

Computer-to-Recorder Interface Error Codes

NOTE: Please consult the operating instructions that accompanied your recorder for additional information.

The following error codes are displayed on the computer during the PC-Card or Tape initialization sequence.

Code	Possible Cause	Type of Problem
1	Wrong number of parameters passed by the host application	software
2	Data-file error.	software
3	Info-file error.	software
4	Pacer-file error.	software
5	Timeout during disk transfer	hardware
6	Disk did not respond to power-up test and/or disk erase procedure failed.	hardware
7	No disk detected.	hardware
8	RTC/NVM write error.	hardware

Code	Possible Cause	Type of Problem
9	Drive power-down error.	hardware
10	Excessive errors during disk read.	hardware
11	Unable to read cylinder index from drive.	hardware
12	Failure to read time from UPLD.DAT info file.	hardware or software
13	Unable to build header file.	software
14	Unable to build event file.	software
15	Initialization failure.	hardware or software
16	Initialization failure (pacer-data area).	hardware or software
17	Initialization failure (time/mode verification failure).	hardware or software
18	Mode information has been corrupted (check connections). Batteries were removed and reinstalled during recording.	hardware
20	Recorder does not contain data for procedure requested.	
23	Requested 2-channel data - recorder contains 3-channel data.	
24	Invalid data request.	
30	Recorder type is not capable of combined-mode operation.	
41	Did not detect recorder.	hardware
48	Did not find disk interface board	hardware
255	Poor or no data on recorder	
1368	Copy protection violation	
1369	Copy protection violation	

Printing Problems

Most printing problems will result in a message displayed on the screen. Consult the operating instructions for your printer to troubleshoot these problems.

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Burdick, Inc., 500 Burdick Parkway, Deerfield, WI 53531 U.S.A. (608) 764-1919